# **EXHIBIT D**

	Page 1
IN THE COURT OF CO PHILADELPHIA	-
) IN RE: PELVIC MESH ) LITIGATION )	FEBRUARY TERM 2014
MASTER DOCKET )	NO. 829
ELLA EBAUGH and ) MARVIN EBAUGH )	COURT OF COMMON PLEAS
Plaintiffs, )	PHILADELPHIA COUNTY
-vs-	
ETHICON WOMEN'S HEALTH ) AND UROLOGY, A DIV. OF ) ETHICON, INC., ET AL., )	JULY TERM 2013 NO. 00866
Defendants. )	
·)	

The videotaped de bene esse deposition of BRUCE ALAN ROSENZWEIG, M.D., called for examination, taken before CORINNE T. MARUT, C.S.R. No. 84-1968, Registered Professional Reporter and a Certified Shorthand Reporter of the State of Illinois, at the JW Marriott Chicago, 151 West Adams Street, Chicago, Illinois, on July 14, 2017, commencing at 9:10 a.m.

Page 2	Page 4
1 APPEARANCES:	1 EXHIBITS (Continued)
2 ON BEHALF OF THE PLAINTIFFS: 3 AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC	2 EXHIBITS PREVIOUSLY MARKED FIRST REFERRED TO
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16	14 P1572 84
17 ALSO PRESENT:	P1801
18	P2377 165
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<ul> <li>19 Anderson Law Offices;</li> <li>20 THOMAS BODYZIAK, Trial Technician.</li> </ul>	17
21	19
VIDEOTAPED BY: MILO SAVICH	20 21
23	22
REPORTED BY: CORINNE T. MARUT, C.S.R. No. 84-1968	23 24
Page 3	Page 5
1 INDEX 2 BRUCE ALAN ROSENZWEIG, M.D. EXAMINATION	1 THE VIDEOGRAPHER: We are now on the record.
3 BY MR. THORNBURGH 12	2 My name is Milo Savich and I am a videographer for
4	3 Golkow Technologies.
5	4 Today's date is July 14, 2017 and the
CONFERENCE CALL WITH JUSTICE GREENSPAN 6 Pages 102 to 112	5 time is 9:10 a.m.
7	6 This video deposition is being held in
EXHIBITS	7 Chicago, Illinois in the matter of Ella
8	8 Cederberg-Ebaugh vs. Ethicon, Inc. et al., which is
BR-Secur EXHIBIT MARKED FOR ID 9	9 being heard in the Court of Common Pleas of
No. 1 "Summary of Opinions" slide 30	10 Philadelphia County, Pennsylvania. The case number
10	11 is 1307-00866.
No. 2 "Materials Reviewed" slide 32	12 The deponent is Dr. Bruce Rosenzweig.
No. 2. "Testimon, Parismally, 25	1
No. 3 "Testimony Reviewed by 35  12 Dr. Rosenzweig" slide	Will counsel please identify themselves
13 No. 4 "TVT-Secur" slide 39	14 for the record.
14 No. 5 Binder of various Plaintiffs' 78	15 MR. THORNBURGH: Daniel Thornburgh for the
Exhibits referred to by	16 Plaintiff.
deponent	17 MR. SNELL: Burt Snell for the Defendants
(see First Referred to 16 Exhibits below)	18 Ethicon and Johnson & Johnson.
10 Exhibits below) 17	19 MR. ROSENBLATT: Paul Rosenblatt for the
18	20 Defendants Johnson & Johnson and Ethicon, Inc.
19	21 THE VIDEOGRAPHER: The Court Reporter is Corey
20	
21 22	22 Marut who will now swear in the witness and we may
23	23 then proceed.
24	24 (WHEREUPON, the witness was duly
1 ==	

2 (Pages 2 to 5)

Page 6 Page 8 1 sworn.) 1 in Federal Court subject to the restrictions of the 2 MR. SNELL: This is counsel for Ethicon and 2 Federal Rules, including Rule 32. 3 3 Johnson & Johnson. Mr. Thornburgh and I had a Also in federal practice under 4 discussion before the deposition and I advised that 4 FRCP 26(b), the scope of a deposition is 5 I had an objection to put on the record, so I'd 5 concomitant with the scope of discovery. 6 like to do that now. 6 Objections are typically limited to 7 7 those that might be waived if not made at the time I want to put an objection on the record 8 to the use of this de bene esse deposition taken in 8 under Rule 32(d)(3), i.e., objections to the manner 9 9 the Ebaugh case in Pennsylvania State Court from of taking the deposition, the form of a question or 10 being used in any Federal MDL trials. 10 answer, the oath or affirmation, a party's conduct 11 To date, no Plaintiff in the Federal MDL 11 and other matters that might be immediately 12 has yet attempted to use Dr. Rosenzweig's 12 corrected. 13 Pennsylvania TVT Carlino deposition in lieu of a 13 With the knowledge that it will be a 14 live trial appearance in Federal Court. 14 de bene esse deposition for Ebaugh, Ethicon's 15 To the extent that any Plaintiff 15 attorneys will have different strategic 16 16 attempts to use in a federal trial the Carlino or considerations for Dr. Rosenzweig's Ebaugh 17 17 Ebaugh deposition transcript in lieu of a live deposition than it would in a typical Federal Court 18 appearance, Defendants will move to strike and 18 deposition. 19 quash the use of these depositions. 19 It's inherently fair -- unfair and 20 20 Plaintiffs' cross-notice of prejudicial for Ethicon to be forced to compromise 21 21 Dr. Rosenzweig's deposition is improper because the its strategy for the de bene esse deposition for 22 Ebaugh deposition is a Pennsylvania de bene esse 22 the purposes of a Federal Court discovery 23 deposition for many reasons. 23 deposition or vice versa, for example, Ethicon may 24 The Ebaugh deposition of Dr. Rosenzweig 24 choose to forego certain objections. Ethicon Page 7 Page 9 1 is a de bene esse deposition, also known as a trial 1 should not be forced into this dilemma by 2 deposition. A de bene esse deposition is a 2 Plaintiffs' improper cross-notice. 3 3 substitute for live testimony at trial and is Additionally and finally, 4 conducted under the Trial Rules of Evidence rather 4 Dr. Rosenzweig, the witness, is not unavailable in 5 5 than as a discovery deposition. the federal cases. He has testified before in the 6 Thus, the Ebaugh deposition will be 6 federal trials. He's typically paid, upon my 7 conducted pursuant to the Pennsylvania Trial Rules 7 information, approximately \$10,000 a day to testify 8 8 of Evidence, not the Federal Rules for discovery. at trial and he has testified in numerous MDL cases 9 There are significant differences between the 9 as well as other State Court cases around this 10 Pennsylvania Rules of Evidence and procedure which 10 country for this litigation as well as other 11 will govern the de bene esse deposition in the 11 manufacturers litigation. 12 Ebaugh trial case as compared to the Federal Rules, 12 MR. THORNBURGH: Are you done? 13 and these differences can affect lines of 13 MR. SNELL: Finally, Ethicon should not be 14 14 questioning, including strategic cross-examination forced to refrain -- reframe their de bene esse 15 decisions. 15 deposition to focus on federal Daubert issues as 16 There are other significant evidentiary 16 opposed to the Frye issues in Pennsylvania. 17 differences between Federal Court and Pennsylvania 17 In sum, the Ebaugh deposition has 18 18 with regard to the use of learned treatises and different -- a different purpose, different issues 19 expert reliance materials. 19 and will be taken under different rules of 20 Also, the Fourth Circuit, as noted in 20 evidence, subject to different pretrial rulings and 21 Tatman v. Collins, the Federal Rules of Civil 21 falls under a different expert standard. 22 Procedure do not distinguish between depositions 22 Plaintiffs' improper cross-notice 23 23 taken for discovery and depositions taken for seeking to have this deposition apply to all cases 24 trial, rather. A deposition may be used at trial 24 in the MDL should be rejected.

#### Page 10 Page 12 1 For the reasons just discussed, in the 1 MR. SNELL: No. Thank you very much. 2 event that any Federal MDL Plaintiff attempts to 2 BRUCE ALAN ROSENZWEIG, M.D., 3 3 use Dr. Rosenzweig's TVT de bene esse deposition called as a witness herein, having been first duly 4 taken in the Carlino Pennsylvania case or his 4 sworn, was examined and testified as follows: 5 TVT-Secur de bene esse deposition taken in the 5 DIRECT EXAMINATION 6 Ebaugh Pennsylvania State Court case in lieu of 6 BY MR. THORNBURGH: 7 live testimony, Ethicon will move to strike and 7 Q. Good morning, Dr. Rosenzweig. 8 quash the use of the designations. 8 A. Good morning. 9 9 Q. How are you doing? And I thank you for your indulgence. 10 MR. THORNBURGH: First of all, this is Dan 10 A. Fine, thank you. 11 Thornburgh for the Plaintiff. 11 Q. Good. Would you please briefly -- would 12 This is the first time that I'm being 12 you please state your name to the ladies and 13 13 made aware of an objection, a quite lengthy gentlemen of the jury. 14 objection, by Defendants being made with respect to 14 A. Bruce Alan Rosenzweig. 15 the current Notice in the Ebaugh matter as well as 15 Q. Now, Dr. Rosenzweig, you've already 16 16 provided trial testimony concerning the TVT-R and the cross-notice that was filed several weeks ago. 17 17 TVT-O devices, correct? So, we obviously haven't had an 18 opportunity to read the brief or motion that was 18 A. Correct. 19 just read into the record at length for the first 19 Q. And those have been preserved, to the 20 time, just for the very first time right before 20 best of your understanding, by video? 21 21 this deposition is about to begin. A. Yes. 22 So, our position is that we can handle 2.2 Q. And as defense counsel alluded to before 23 this objection later, but we also should be able to 23 we -- on the record, we have an agreement that we 24 handle quite efficiently the issues that were 24 will not, at least in the Ebaugh case, but I think Page 11 Page 13 1 addressed by cross-counsel by editing video and 1 that agreement should extend beyond that, to not 2 cutting video so that it complies with either the 2 cover old ground or cover your trial testimony that 3 Federal Rules or with the Pennsylvania State Rules. 3 you've provided in the prior preservation 4 4 videotaped depositions in Carlino and so forth. And that's it. 5 5 MR. SNELL: I'll just reply that these issues MR. SNELL: Since you do raise that, I will 6 were initially raised before the Carlino TVT trial 6 make a statement with regards to --7 deposition of Dr. Rosenzweig by the defense where 7 MR. THORNBURGH: You did already. 8 8 there it was noticed by Plaintiffs to be a TVT, MR. SNELL: With regard to the TVT-O. I think 9 TVT-O and TVT-Secur deposition and these issues 9 you threw in TVT-O. And it's my position as I've 10 were raised and objections were filed and as I 10 indicated to Plaintiffs' counsel that I do not 11 understand the judge held a hearing and did not 11 believe the TVT-O deposition in the Ramirez Texas 12 reach all those issues. 12 case, State Court case, was a part of that 13 The judge's ruling at the hearing was to 13 continuation. 14 the parties to just go forward at that time and 14 But counsel and I have agreed that for 15 proceed and do Dr. Rosenzweig's de bene esse TVT 15 Pennsylvania, and my position is for Pennsylvania 16 Carlino deposition, which we accomplished in 16 obviously only, for the Pennsylvania mass tort 17 December 2015 and January 2016 as I recall. 17 program that we both agree we don't have to recover 18 MR. THORNBURGH: And I appreciate that 18 issues covered in Carlino and that both sides can 19 position, but obviously there was no formal 19 designate testimony from the Carlino TVT deposition 20 objection filed with respect to the Notice of 20 and each side maintains its objections, and that's 21 Deposition and Cross-Notice of Deposition for which 21 my position to your position. 22 brings us here today for the deposition, 22 MR. THORNBURGH: We obviously have a different 23 preservation deposition of Dr. Rosenzweig. 23 position. We believe that Ramirez and Carlino 24 Anything further, counsel? 24 preservation depos can be used as preservation

#### Page 14 Page 16 1 depos, depositions for the purposes of cutting 1 side can designate from the TVT Carlino 2 video for either Ebaugh or other cases. 2 de bene esse deposition, so we don't have to redo 3 3 MR. SNELL: Okay. I understand your position. everything previously covered with him in this 4 I just want to make sure mine was clear so that we 4 TVT-Secur de bene esse deposition, is okay. And I 5 5 said both parties preserve their objections. Okay? understood. 6 6 And I didn't hear back from And I don't plan to be duplicative, but 7 7 there are some things that I will have to get into Mrs. Baldwin. And I did copy you. So I appreciate 8 that have been covered in Carlino because of the 8 that. That last e-mail was July 12, 7:52 p.m. 9 9 nature of this and I'm sure your examination. MR. THORNBURGH: Which my interpretation of that is that you weren't objecting. But anyway. 10 BY MR. THORNBURGH: 10 11 Q. The point is, Doctor, you've already 11 We can take that up later on. 12 provided preservation testimony in the Ramirez and 12 BY MR. THORNBURGH: 13 13 Carlino matters, correct? Q. So, Dr. Rosenzweig, you've already 14 A. Correct. 14 provided prior testimony, and I will not attempt to 15 15 Q. And we -- I will attempt not to cover ask you questions that you've already been asked at 16 16 the issues or testimony that you've already those prior depositions. Okay? 17 provided in those other cases? 17 A. Thank you. 18 A. Thank you. 18 Q. But we are here regarding the TVT-Secur, 19 MR. THORNBURGH: And, counsel, because no 19 is that correct? 20 20 formal objection was made with respect to these two A. Correct. 21 21 Notices in this case, the Notice in Ebaugh for the Q. And are you prepared to offer your 22 deposition and the Cross-Notice in the MDL, I've 22 expert opinions concerning the TVT-Secur device? 23 prepared under the assumption that we would be able 23 A. Correct. 24 24 to use some of the testimony from those prior Q. How did you become familiar -- strike Page 15 Page 17 1 1 preservation cases. that. 2 MR. SNELL: Okay. And I understand that. And 2 Are you familiar with the TVT-Secur 3 3 as you know, just so the record is clear, I did system? 4 e-mail you and Ms. Baldwin who is Pennsylvania 4 A. Yes. 5 5 counsel about this issue and I raised that with Q. And how did you first become familiar 6 regard to the TVT-O, that was a Ramirez Texas State 6 with the TVT-Secur system? 7 Court case and did not fall under this agreement. 7 MR. SNELL: Can I interrupt you and ask you 8 8 one question just for clarity. So, are you relying But I did also say I am fine with both 9 sides agreeing and being able to designate from the 9 on his qualifications back in TVT Carlino --10 TVT Carlino deposition in Pennsylvania for this 10 MR. THORNBURGH: Yeah. I am. 11 MR. SNELL: -- for the basis of this? 11 12 MR. THORNBURGH: I didn't see any e-mail from 12 MR. THORNBURGH: I am. 13 you. I'm not saying you didn't. You don't have to 13 MR. SNELL: For this. 14 go find it. 14 MR. THORNBURGH: I am. Do you have an 15 MR. SNELL: Okay. 15 objection to relying --16 MR. THORNBURGH: I didn't see any e-mail from 16 MR. SNELL: Yes. 17 you that explicitly argued or held the position 17 MR. THORNBURGH: -- on his testimony about his 18 that the Ramirez preservation deposition would not 18 qualifications? 19 be -- that we would not be -- or that you were 19 MR. SNELL: No, I don't have any -- I don't 20 objecting to the use of that at other trials. 20 have any objection to you relying on those 21 MR. SNELL: Okay. Well, July 12, 2017, 2:15 21 qualifications. 22 p.m. is when I sent that e-mail and then my MR. THORNBURGH: Are you going to have an 22 23 follow-up to it where I stated I am okay with 23 objection --24 agreeing that in the Pennsylvania cases that either 24 MR. SNELL: We very well may have an objection

5 (Pages 14 to 17)

	Page 18		Page 20
1	at trial.	1	properly before us within even Pennsylvania.
2	MR. THORNBURGH: Here's the problem. Here's	2	But I just want to understand if you
3	where I am prejudiced because I have prepared to	3	were going to if you weren't going to do
4	ask questions today and rely on the testimony	4	anything on qualifications and you were going to go
5	concerning his qualifications	5	right to substance. That's all I was trying to
6	MR. SNELL: I'm fine with that.	6	understand.
7	MR. THORNBURGH: so we don't have to cover	7	MR. THORNBURGH: I'm going to try to jump
8	the same background, training and experience he's	8	mostly into substance. I am going to talk a little
9	already testified to in other cases.	9	bit about his qualifications with Secur with an
10	MR. SNELL: And I'm okay with that. I just	10	understanding that we can at least use the Carlino
11	want to understand and make sure that that's what	11	testimony concerning his background and
12	you were doing because you kind of jumped into	12	qualifications.
13	substantive things.	13	MR. SNELL: Yes. And I am totally fine with
14	MR. THORNBURGH: That's the next thing I was	14	that.
15	going to say, so we won't cover your background,	15	MR. THORNBURGH: Okay. Hopefully we won't
		16	, , , , , , , , , , , , , , , , , , ,
16 17	knowledge and training.  MR. SNELL: As you know, in Pennsylvania you	17	have interruptions and objections throughout the rest of this de bene esse deposition because it's
18	actually have to formally take the step and qualify	18	going to take us a week to finish.
19	an expert before.	19	MR. SNELL: I didn't mean to. I mean, it's
20	MR. THORNBURGH: I understand that. But we	20	because of the unique way that Pennsylvania does it
21	are not going on we are relying on the testimony	21	versus MDL and because I thought you were just
22	he's provided	22	jumping, that's the only reason I wanted to make
23	MR. SNELL: Got you.	23	sure I understood.
24	MR. THORNBURGH: concerning his knowledge,	24	As I said, your qualifications, I
	Page 19		Page 21
1	training and experience in the prior cases.	1	understand you are using that from Carlino. I
2	Now, we will also talk about his	2	don't have a problem with that. If we have
3	qualifications today to talk about the TVT-Secur	3	objections to that part, they will be objections
4	device.	4	that we've always had just like you would have
5	So, it's sort of two steps, right. He's	5	objections to our qualifications cross of him if
6	given a background, training he's testified	6	you had it.
7	about his background, training and experience and	7	MR. THORNBURGH: Right.
8	qualifications in prior preservation depositions.	8	MR. SNELL: That's the reason I butted in.
9	Right?	9	I'm sorry.
10	MR. SNELL: Yes.	10	MR. THORNBURGH: Just to make one quick
11	MR. THORNBURGH: On the TVT-O and	11	statement. It's our position that we can use
12	TVT Retropubic devices. This is a TVT-R, so I'm	12	Carlino and Ramirez. You said Carlino, but we will
13	going to briefly talk about his experience with the	13	handle that we will take that up later on.
14	TVT-Secur.	14	BY MR. THORNBURGH:
15	MR. SNELL: Okay. Okay.	15	Q. All right, Doctor. How did you first
16	MR. THORNBURGH: But I understand that you're	16	become familiar with the TVT-Secur system?
17		17	A. I was first introduced to the TVT-Secur
18	going to object later on to us playing video from the either the Carlino or Ramirez cases with	18	by Ethicon sales representatives. They showed me
		19	promotional material and that's how I first became
19	respect to his testimony about his qualifications?	20	introduced to the TVT-Secur.
20	MR. SNELL: No.	21	
21	MR. THORNBURGH: Okay.		Q. And when approximately did you first
22	MR. SNELL: I don't have a problem with	22	become introduced and familiar with the TVT-Secur
23	Carlino, as I've stated, right. I do have a	43	system?
	11 MD 1 D 1 T 1 M 1 1	24	A If I recall it was machable late 2006
24	problem with Ramirez. Ramirez I don't believe is	24	A. If I recall, it was probably late 2006,

6 (Pages 18 to 21)

#### Page 22 Page 24 1 but it might have been early 2007. 1 into any of your patients? 2 Q. Okay. And you've testified previously 2 A. I have not used the TVT-Secur device on 3 3 about the TVT Retropubic and the TVT-Obturator one of my patients. 4 devices. But the TVT-Secur system, can you briefly 4 Q. And why is that? 5 explain what it is and what it is intended to 5 A. When I was first introduced to it, 6 6 frankly, I didn't think it would work. 7 7 Q. And is that after you had an opportunity A. The TVT-Secur system is a device that is 8 used to treat stress urinary incontinence. I've 8 to speak with the sales representatives and look at 9 9 already described for the jury stress urinary the actual physical device? 10 incontinence and the concept of a midurethral sling 10 MR. SNELL: Object; leading. 11 used for stress urinary incontinence. 11 BY MR. THORNBURGH: 12 The TVT-Secur device is what's known as 12 Q. What led you to that conclusion, Doctor? 13 13 a single-incision sling meaning that there's a A. Not only looking at the promotional 14 vaginal incision and there are no exit points as I 14 material but also looking at the device. 15 described for the other what's called full-length 15 Q. And as part of your treatment of 16 sling. So, this is a shorter sling. 16 patients, did you ever treat any patients who 17 It's still made out of the same 17 experienced complications as a result of the 18 polypropylene. It still has the same 18 TVT-Secur device? 19 19 characteristics that I've described as being A. Yes, I have. I've previously described 20 heavy-weight, small-pore polypropylene. It is used 20 for the jury my experience in treating 21 to treat the same condition which is stress urinary 21 complications of midurethral slings and that 22 incontinence and it's placed in the same position, 22 includes also treating complications of the TVT-Secur device. 23 which is the midurethra. 23 24 However, those are where the 24 MR. SNELL: Object. Non-responsive. Page 23 Page 25 similarities between what I have described before 1 BY MR. THORNBURGH: 1 2 as the full-length midurethral sling such as the 2 Q. And with respect to those complications, 3 3 TVT and the TVT-Obturator is that it is a could you briefly -- I know you've testified about 4 4 complications associated with these -- with the heavier -- excuse me -- a stiffer, shorter sling 5 5 that had never been used before. full-length midurethral slings like the 6 6 TVT Retropubic and TVT-Obturator, but how are those The length is 8 centimeters. That 7 length had never been used before in a midurethral 7 complications impacted, if at all, by the TVT-Secur 8 8 device? 9 It was cut by a laser. I've already 9 A. I've treated complications associated 10 given testimony about the difference between 10 with the TVT-Secur device both surgically by mechanical-cut and laser-cut. And that had never 11 11 removing either a portion of the device when they 12 12 been used before. cause complications or the majority of the device. 13 It has an arrowhead introducer to get 13 I also treat complications without 14 the short, rigid mesh into the position to act as 14 surgery using modalities such as therapies inside part of the midurethra. That had never been used 15 15 the vagina to treat pain, pain with intercourse, 16 before. 16 also doing blocking nerves that can treat the pain 17 And the ends of the short, rigid mesh 17 associated with the midurethral slings including 18 have a dissolvable fleece tip. That had never been 18 the Secur and pain with intercourse. 19 used before. 19 I've also treated patients with things 20 Q. And we're going to get into more 20 like biofeedback, electrical stimulation, physical 21 specifics of those design characteristics 21 therapy for problems with voiding dysfunction 22 throughout the day. But did you ever -- can you 22 meaning that they can't empty their bladder 23 tell the ladies and gentlemen of the jury whether 23 completely or from entities such as overactive 24 or not you've ever implanted a TVT-Secur device 24 bladders, which the patient has an irritation of

	Page 26		Page 28
1	their bladder which makes them need to void	1	IFU?
2	frequently, urgently or get up at night to void.	2	A. Yes.
3	Q. Now, as part of your treatment of	3	Q. And was your review of the Information
4	patients who were experiencing complications from a	4	for Use for the TVT-Secur helpful to you in
5	Secur device, TVT-Secur device, did you have to	5	treating the complications that your patients were
6	become familiar with the TVT-Secur system?	6	experiencing?
7	A. Yes.	7	A. Well, the Instructions for Use, again,
8	Q. And what did you do to become familiar	8	gives information about how to use the device, how
9	with the TVT-Secur system?	9	to implant the device. But it does not contain
10	A. I looked at again the promotional	10	information on how to treat complications or how to
11	brochures. I reviewed the Instructions for Use,	11	remove the device.
12	which is a pamphlet that comes with each device. I	12	Q. And have you been qualified as an expert
13	discussed this with colleagues of mine.	13	witness in any federal courts in the United States?
14	Also, I have looked at internal Ethicon	14	A. Yes.
15	documents, internal or deposition testimony from	15	Q. And have you been where have you been
16	key Ethicon employees, both scientists and Medical	16	qualified, if you can recall?
17	Directors, and a review of the scientific	17	A. In West Virginia and North Carolina.
18	literature.	18	Q. And have you been qualified as an expert
19	Q. Did you have an opportunity to see if	19	to offer opinions on the same topics that we're
20	the IFU or the Information for Use for the Secur	20	speaking about here today in any State Court in the
21	device strike that.	21	United States?
22	In your private practice did you have an	22	A. Yes.
23	opportunity, I think you've testified to this	23	Q. And what courts specifically?
24	already, but did you have an opportunity to review	24	A. In California, Missouri, Texas and here
	Page 27		Page 29
1	Page 27 the Information for Use related to the TVT-Secur	1	Page 29 in Philadelphia.
1 2		1 2	
	the Information for Use related to the TVT-Secur		in Philadelphia.
2	the Information for Use related to the TVT-Secur device?	2	in Philadelphia.  Q. And have you been qualified as an expert
2	the Information for Use related to the TVT-Secur device? MR. SNELL: Object; leading.	2	in Philadelphia.  Q. And have you been qualified as an expert witness to offer expert opinion testimony with
2 3 4	the Information for Use related to the TVT-Secur device?  MR. SNELL: Object; leading. BY THE WITNESS:	2 3 4	in Philadelphia.  Q. And have you been qualified as an expert witness to offer expert opinion testimony with respect to the TVT-Secur device specifically?
2 3 4 5	the Information for Use related to the TVT-Secur device?  MR. SNELL: Object; leading.  BY THE WITNESS:  A. Yes.	2 3 4 5	in Philadelphia.  Q. And have you been qualified as an expert witness to offer expert opinion testimony with respect to the TVT-Secur device specifically?  A. Yes.
2 3 4 5 6	the Information for Use related to the TVT-Secur device?  MR. SNELL: Object; leading.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:	2 3 4 5 6	in Philadelphia.  Q. And have you been qualified as an expert witness to offer expert opinion testimony with respect to the TVT-Secur device specifically?  A. Yes.  Q. In what courts?
2 3 4 5 6 7	the Information for Use related to the TVT-Secur device?  MR. SNELL: Object; leading.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:  Q. Because I got an objection, let me ask	2 3 4 5 6 7	in Philadelphia.  Q. And have you been qualified as an expert witness to offer expert opinion testimony with respect to the TVT-Secur device specifically?  A. Yes.  Q. In what courts?  A. In Philadelphia.
2 3 4 5 6 7 8	the Information for Use related to the TVT-Secur device?  MR. SNELL: Object; leading.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:  Q. Because I got an objection, let me ask again.	2 3 4 5 6 7 8	in Philadelphia.  Q. And have you been qualified as an expert witness to offer expert opinion testimony with respect to the TVT-Secur device specifically?  A. Yes.  Q. In what courts?  A. In Philadelphia.  Q. Now, Doctor, in the course of the
2 3 4 5 6 7 8 9	the Information for Use related to the TVT-Secur device?  MR. SNELL: Object; leading.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:  Q. Because I got an objection, let me ask again.  What is a the IFU?	2 3 4 5 6 7 8	in Philadelphia.  Q. And have you been qualified as an expert witness to offer expert opinion testimony with respect to the TVT-Secur device specifically?  A. Yes.  Q. In what courts?  A. In Philadelphia.  Q. Now, Doctor, in the course of the testimony that you'll be providing today, do you
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	Page 30		Page 32
1	discussing many of the materials that you reviewed	1	The Defendants defectively designed the
2	in this case. But before we do that, can you tell	2	TVT-Secur system.
3	the jury whether or not you came to any conclusions	3	Q. Now, in can you explain to the ladies
4	or opinions about the TVT-Secur device?	4	and gentlemen strike that.
5	A. Yes, I did.	5	Can you explain to the ladies and
6	Q. And did you prepare a slide summarizing,	6	gentlemen of the jury what you were asked to do in
7	briefly summarizing, those opinions that will help	7	this case?
8	you explain those opinions to the jury?	8	A. I was asked to review materials and
9	A. Yes, I did.	9	deposition testimony, the literature, to review the
10	MR. THORNBURGH: Tom, can we go ahead and show	10	design, the development and the testing of the
11	Slide No. 1.	11	TVT-Secur device.
12	MR. SNELL: Do you have a copy, counsel?	12	Q. And did you prepare a slide that would
13	MR. THORNBURGH: Yes, I do.	13	assist you in explaining to the jury the materials
14	BY MR. THORNBURGH:	14	that you reviewed and relied upon in offering your
15	Q. I will go ahead and mark as I think we	15	opinions?
16	will call it R I'm sorry BR-Secur 1, which is	16	A. Yes.
17	the summary of your opinions in this slide.	17	Q. Let's go ahead and mark as Exhibit
18	(WHEREUPON, a certain document was	18	and we'll call it BR-Secur 2. But this is the
19	marked as BR-Secur Exhibit No. 1:	19	slide that you prepared.
20	Summary of Opinions slide.)	20	(WHEREUPON, a certain document was
21	MR. SNELL: Are you intending at trial to put	21	marked as BR-Secur Exhibit No. 2:
22	this up as basically as it looks or bullet points	22	Materials Reviewed slide.)
23	as we go along?	23	BY MR. THORNBURGH:
24	MR. THORNBURGH: We intend to do it a number	24	Q. And what materials did you review in
	Page 31		Page 33
1	of ways, but at this point in the video we would	1	preparation for this case and offering the opinions
2	put this slide up as it is.	2	that you have related to the TVT-Secur device?
3	MR. SNELL: Okay.	3	•
		1 2	MR. SNELL: Ouick objection to the slide.
4	MR. THORNBURGH: This exhibit up as it is.	4	MR. SNELL: Quick objection to the slide, violates Rule 705 facts and bases under
4 5	MR. THORNBURGH: This exhibit up as it is. MR. SNELL: So I object to that, failing Rule		violates Rule 705 facts and bases under
	MR. SNELL: So I object to that, failing Rule	4	· · · · · · · · · · · · · · · · · · ·
5		4 5	violates Rule 705 facts and bases under Pennsylvania law.
5 6	MR. SNELL: So I object to that, failing Rule 705 under Pennsylvania. Go ahead. BY MR. THORNBURGH:	4 5 6 7	violates Rule 705 facts and bases under Pennsylvania law. BY THE WITNESS: A. I reviewed the medical literature from
5 6 7	MR. SNELL: So I object to that, failing Rule 705 under Pennsylvania. Go ahead. BY MR. THORNBURGH: Q. And can you provide the ladies and	4 5 6	violates Rule 705 facts and bases under Pennsylvania law. BY THE WITNESS:
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	Page 34		Page 36
1	A. Yes.	1	pages of witness testimony you've reviewed in
2	Q. And will our discussion include your	2	rendering your opinions in this case?
3	opinions and the support for those opinions from	3	A. Thousands.
4	that are derived from the medical publications?	4	Q. Now, let me ask you this question,
5	A. Yes.	5	Doctor: Were prior to your involvement in this
6	Q. And will we discuss today the opinions	6	litigation had you ever had an opportunity to
7	that you have related to the TVT-Secur device and	7	review Ethicon's internal company documents?
8	the basis for those opinions and support for those	8	MR. SNELL: Objection; form. This is a
9	opinions that are derived from the internal Ethicon	9	this is a backwards way of going at the
10	company documents?	10	confidentiality agreement that the parties entered
11	A. Yes.	11	into with regard to the designation of company
12	Q. And will you offer opinions today	12	documents as confidential.
13	concerning the TVT-Secur device that are supported	13	MR. THORNBURGH: No, it's not.
14	by the depositions of Ethicon and Johnson & Johnson	14	MR. SNELL: That's my position.
15	current and former employees?	15	MR. THORNBURGH: It's not.
16	A. Yes.	16	MR. SNELL: That's my position. Go ahead.
17	MR. SNELL: Object; leading. Go ahead.	17	MR. THORNBURGH: So, let me ask the question
18	BY MR. THORNBURGH:	18	again. I understand the objection, so we don't
19	Q. And with respect to the testimony	19	interrupt again.
20	reviewed by you, did you provide a slide or create	20	BY MR. THORNBURGH:
21	a slide that would assist the jury in understanding	21	Q. Now, before you were retained as an
22	the number of depositions or at least the witnesses	22	expert witness in this case, did Ethicon and
23	for whom you've read and reviewed and rely upon	23	Johnson & Johnson make available to you their
24	their testimony?	24	internal company documents?
	Page 35		Page 37
1	A. Yes.	1	MR. SNELL: Same objection. Go ahead.
2	MR. THORNBURGH: I will go ahead and mark as	2	BY THE WITNESS:
3	BR-Secur 3 a slide presentation.	3	A. No.
4	(WHEREUPON, a certain document was	4	BY MR. THORNBURGH:
5	marked as BR-Secur Exhibit No. 3:	5	Q. In your practice as a treating physician
6	Testimony Reviewed by Dr.	6	did you ever have access to Ethicon or
7	Rosenzweig slide.)	7	Johnson & Johnson's internal company documents?
8	BY MR. THORNBURGH:	8	A. No.
9	Q. Is this the PowerPoint slide that you	9	MR. SNELL: Object; relevance. Go ahead.
10	helped create?	10	BY THE WITNESS:
11	A. Yes.	11	A. No.
12	Q. And does this provide a list of the	12	BY MR. THORNBURGH:
13	witnesses for whom you've reviewed their deposition	13	Q. Why is that?
14	testimony and relied upon their at least in	14	A. They're not available to me.
15	part, for rendering your opinions in this case?	15	Q. Now, what types of literature have
16	A. Yes.	16	you strike that.
17	Q. And do you have an estimate, Doctor, of	17	Does Ethicon make available does
18	how many of those the Ethicon internal documents	18	Ethicon make their internal company documents
19	that you've reviewed strike that.	19	publicly available to treating physicians,
20	Do you have an estimate of how many	20	urogynecologists, gynecologists such as yourself?
21	pages of Ethicon documents you reviewed in this	21	MR. SNELL: Objection; outside the scope of
22	litigation?	22	his expert report. Also objection insofar as it is
23	A. Tens of thousands.	23	not a proper expert basis under Pennsylvania law.
24	Q. And do you have an estimate of how many	24	BY THE WITNESS:
22 23	litigation?  A. Tens of thousands.	22 23	his expert report. Also objection insofar as in not a proper expert basis under Pennsylvania

A. No.  BY MR. THORNBURGH:  Q. And what types of literature have you reviewed in forming your opinions in this case, Doctor?  A. As I've described earlier in prior testimony, I've reviewed the lion's share of the literature on midurelly slings in general and also the TVT-Secur.  Q. Did you use the same methods in this case, in roaching your expert conclusions as you use in your private practice?  A. Yes.  Q. Are you familiar with how the TVT-Secur device in the human body?  A. Yes.  Q. And did you help prepare a slide that illustrates the TVT-Secur device implant locations?  A. Yes.  Q. And would that assist, help you help you assist the jury in understanding more about the TVT-Secur device in the slide entitled "TVT-Secur" state.)  Fage 39  MR. THORNBURGH: I will go ahead and mark as BR-Secur 4 the slide entitled "TVT-Secur" state.)  BY MR. THORNBURGH: I will go ahead and mark as BR-Secur 4 the slide entitled "TVT-Secur" state.)  BY MR. THORNBURGH: I will go ahead and mark as BR-Secur 4 the slide entitled "TVT-Secur" state.)  BY MR. THORNBURGH: I will go ahead and mark as BR-Secur 4 the slide entitled "TVT-Secur" state.)  BY MR. THORNBURGH: I will go ahead and mark as BR-Secur as slide.  BY MR. THORNBURGH: I will go ahead and mark as BR-Secur as a slide.  BY MR. THORNBURGH: I will go ahead and mark as BR-Secur as a slide.  BY MR. THORNBURGH: I will go ahead and mark as BR-Secur as a slide.  BY MR. THORNBURGH: I will go ahead and mark as BR-Secur as a slide.  BY MR. THORNBURGH: I will go ahead and mark as BR-Secur as a slide.  BY MR. THORNBURGH: I will go ahead and mark as BR-Secur as a slide.  BY MR. THORNBURGH: I will go ahead and the same and a slide entitled "TVT-Secur" slide.)  BY MR. THORNBURGH: I will go ahead and mark as BR-Secur as a slide.  BY MR. THORNBURGH: I will go ahead and mark as BR-Secur as a slide.  BY MR. THORNBURGH: I will go ahead and mark as BR-Secur as a slide.  BY MR. THORNBURGH: I will go ahead and mark as BR-Secur as a slide.  BY MR. THORNBURGH: I will go ahead and the secure as a		Page 38		Page 40
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Q. And what types of literature have you reviewed in forming your opinions in this case, bottor?  A. As Ive described earlier in prior testimony, Ive reviewed the lion's share of the literature on midurethral slings in general and also the TVT-Secur.  Q. Did you use the same methods in this case in reaching your expert conclusions as you use lin your private practice?  A. Yes.  Q. Are you familiar with how the TVT-Secur device is designed and how it's supposed to be placed in the human body?  A. Yes.  Q. And did you help prepare a slide that illustrates the TVT-Secur device in what is subject to the form of the tereord.  A. Yes.  A. Thank Yuo. Oav.  Wier RulPoN, discussion was had off the record.  Wier back on the video record.  Wier ba	2	BY MR. THORNBURGH:	2	
4 TVT-Secur was launched towards the end of 5 Poctor? 6 A. As I've described earlier in prior 7 testimony, I've reviewed the lion's share of the 8 literature on midurethral slings in general and 9 also the TVT-Secur. 10 Q. Did you use the same methods in this 11 case in reaching your expert conclusions as you use 12 in your private practice? 13 A. Yes. 14 Q. Are you familiar with how the TVT-Secur 15 device is designed and how it's supposed to be 16 placed in the human body? 17 A. Yes. 18 Q. And you light prepare a slide that 19 illustrates the TVT-Secur device implant locations? 20 A. Yes. 21 Q. And would that assist, help you – help 22 you assist the jury in understanding more about the 23 TVT-Secur procedure? 24 A. Yes. 25 Page 39 26 MR. THORNBURGH: I will go ahead and mark as 26 BR-Secur 4 the slide entitled "TVT-Secur." 27 (WHEREUPON, a certain document was 28 marked as BR-Secur Exhibit No. 4: 29 TVT-Secur' slide.) 20 Do you recognize this document? 31 (WHEREUPON, a certain document was 32 marked as BR-Secur Exhibit No. 4: 33 (WHEREUPON, a certain document was 34 marked as BR-Secur Exhibit No. 4: 35 TVT-Secur slide.) 36 Beptember 07 2006. 37 (WHEREUPON, a certain document was 38 marked as BR-Secur Exhibit No. 4: 39 Q. Is this the slide that you created? 40 A. Yes. 41 Q. And can you go ahead and open that 42 device and let's talk about it briefly: 43 A. Yes. 44 TVT-Secur has been device in the box that it was sold in. 45 A. The first thing that's in the device is 46 what's called the Instructions for Use, which we've 46 device and be placed in two 41 the record.) 41 THE VIDEOGRAPHER: The time is 9:52 a.m. and 46 we've back on the video record. 49 De Doctor, I'm going to hand you the 41 TVT-Secur for the which is indications and any open that device in the box that it was sold in. 40 De Doctor, I'm going to hand you the 41 TVT-Secur for the first talk about it briefly: 41 A. Yes. 42 Q. And can you go ahead and open that 43 device and let's talk about it briefly: 44 A. Yes. 45 TVT-Secur for the first talk abo	3	O. And what types of literature have you	3	
5 Doctor? 6 A. As I've described earlier in prior 7 testimony, I've reviewed the lion's share of the 8 literature on midurethral slings in general and 9 also the TVT-Secur. 10 Q. Did you use the same methods in this 11 case in reaching your expert conclusions as you use 11 in your private practice? 12 Q. Are you familiar with how the TVT-Secur 13 A. Yes. 14 Q. Are you familiar with how the TVT-Secur 15 device is designed and how it's supposed to be 16 placed in the human body? 17 A. Yes. 18 Q. And did you help prepare a slide that 19 illustrates the TVT-Secur device implant locations? 19 A. Yes. 20 Q. And would that assist, help you – help 20 you assist the jury in understanding more about the 21 TVT-Secur procedure? 22 A. Yes. 23 Q. And would that assist, help you – help 24 A. Yes. 25 BR-Secur 4 the slide entitled "TVT-Secur." 26 BY MR. THORNBURGH: I will go ahead and mark as 2 BR-Secur 4 the slide entitled "TVT-Secur." 27 Q. Doctor, I'm going to hand you the 28 TVT-Secur' slide.) 29 Q. Is this the slide that you created? 30 Q. Is this the slide that you created? 41 Q. Okay. And what is the jury secing in 42 A. Yes. 43 Condition of the TVT-Secur fusion of the procedure as slide. 44 A. Yes. 45 TVT-Secur' slide.) 46 BY MR. THORNBURGH: 10 Q. Doctor, I'm going to hand you the 47 TVT-Secur' slide.) 48 A. Yes. 49 Q. Is this the slide that you created? 40 Q. Doctor, which is called the position, and the other - the same the device and let's talk about it briefly. 40 A. Ves. 41 Q. And can you go ahead and open that device and let's talk about it briefly. 41 A. Yes. 42 Q. And can you go ahead and open that device and let's talk about it briefly. 43 A. Yes. 44 C. Then fixed the very described earlier. The device is what is indications are, who it should not be used on, which is contraindications. It describes the device. 44 A. Yes. 45 TVT-Secur' slide.) 46 PY MR. THORNBURGH: 10 PY Secur the same the device and let's talk about it briefly. 47 A. Yes. 48 Condition of the first and second of the procedure of the procedure	4		4	•
6 A. As I've described earlier in prior 7 testimony, I've reviewed the lion's share of the 8 literature on midurethral slings in general and 9 also the TVT-Secur. 10 Q. Did you use the same methods in this 11 case in reaching your expert conclusions as you use 12 in your private practice? 13 A. Yes. 14 Q. Are you familiar with how the TVT-Secur 15 device is designed and how it's supposed to be 16 placed in the human body? 17 A. Yes. 18 Q. And did you help prepare a slide that 19 illustrates the TVT-Secur device implant locations? 20 A. Yes. 21 Q. And would that assist, help you – help 22 you assist the jury in understanding more about the 23 TVT-Secur procedure? 24 A. Yes. 25 BR-Secur 4 the slide entitled "TVT-Secur." 26 (WHEREUPON, a certain document was marked as BR-Secur Establist No. 4: 27 TVT-Secur' slide.) 28 BR-Secur 4 the slide entitled "TVT-Secur." 39 (WHEREUPON, a certain document was marked as BR-Secur Establist No. 4: 40 TVT-Secur' slide.) 41 Q. And can you go ahead and open that device and let's talk about it briefly. 42 A. Yes. 43 A. Yes. 44 Q. And can you go ahead and open that device and let's talk about it briefly. 45 "TVT-Secur' slide.) 46 BY MR. THORNBURGH: 47 Q. Do you recognize this document? 48 A. Yes. 49 Q. Is this the slide that you created? 40 A. Yes. 41 Q. Okay. 42 Q. And can you go ahead and open that device and let's talk about it briefly. 41 A. Yes. 42 Q. And can you go ahead and open that device and let's talk about it briefly. 42 Q. Okay. 43 A. Thank you. 44 C. Treatly quick. 45 TTHE VIDEOGRAPHER: The time is 9:52 a.m. and we're back on the video record. 46 TWT-Secur device implant locations? 47 Q. Do ton, I'm going to hand you the TVT-Secur device in the box that it was sold in. 48 A. Yes. 49 Q. And can you go ahead and open that device and let's talk about it briefly. 40 Q. Okay. 41 A. Thank you. 41 Q. And can you go ahead and open that device and let's talk about it briefly. 41 A. Well, the TVT-Secur can be placed in two different fashions, on to resemble the fundamental device			5	September of 2006, if I recall correctly was
restimony, I've reviewed the lion's share of the literature on midurethral slings in general and a slo the TVT-Secur.  Q. Did you use the same methods in this case in reaching your expert conclusions as you use in your private practice?  12 in your private practice?  13 A. Yes.  14 Q. Are you familiar with how the TVT-Secur device is designed and how it's supposed to be placed in the human body?  15 device is designed and how it's supposed to be placed in the human body?  16 Q. And did you help prepare a slide that illustrates the TVT-Secur device implant locations?  18 Q. And did you help prepare a slide that illustrates the TVT-Secur device implant locations?  19 WHEREUPON, discussion was had off the record.  19 WHEREUPON, discussion was had off the record.  19 WHEREUPON, discussion was had off the record.  10 WHEREUPON, discussion was had off the record.  11 WIDEOGRAPHER: The time is 9:52 a.m. and we are going off the video record.  12 Q. Doctor, modified the record and we are going off the video record.  13 THE VIDEOGRAPHER: The time is 9:52 a.m. and we are going off the video record.  14 A. Yes.  15 WHEREUPON, discussion was had off the record.  16 the record.  17 WHEREUPON, discussion was had off the record.  18 MR. THORNBURGH:  18 the VIDEOGRAPHER: The time is 9:52 a.m. and we are going off the video record.  19 WHEREUPON, discussion was had off the record.  19 WHEREUPON, discussion was had off the record.  10 WHEREUPON, discussion was had off the record.  11 WHEREUPON, discussion was had off the record.  12 Q. Doctor, Pm going to hand you the TVT-Secur device in the box that it was sold in.  14 A. Yes.  15 Q. And can you go ahead and open that device and let's talk about it briefly.  26 WHEREUPON, a certain document was marked as BR-Secur Exhibit No. 4:  27 TYT-Secur device in the box that it is should be used on or what it is indications are, who it should not be used on, which is contraindications. It describes the device even and warnings associated with the device even and warnings associated with t			1	
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9 also the TVT-Secur. 10 Q. Did you use the same methods in this 11 case in reaching your expert conclusions as you use 12 in your private practice? 13 A. Yes. 14 Q. Are you familiar with how the TVT-Secur 15 device is designed and how it's supposed to be 16 placed in the human body? 16 A. Yes. 17 A. Yes. 18 Q. And did you help prepare a slide that 19 illustrates the TVT-Secur device implant locations? 20 A. Yes. 21 Q. And would that assist, help you — help 22 you assist the jury in understanding more about the 23 TVT-Secur procedure? 24 A. Yes. 25 Page 39 26 BR-Secur 4 the slide entitled "TVT-Secur." 26 WIFEREUPON, a certain document was 27 marked as BR-Secur Exhibit No. 4: 28 BR-Secur 4 the slide entitled "TVT-Secur." 39 (WIFEREUPON, a certain document was 40 marked as BR-Secur Exhibit No. 4: 50 "TVT-Secur brock of the first and second generation 19 it together as a slide. 10 Q. Okay. 11 THE VIDEOGRAPHER: The time is 9:52 a.m. and 11 were back on the video record. 12 WIFEREUPON, discussion was had off 13 the record. 14 THE VIDEOGRAPHER: The time is 9:52 a.m. and 15 Were back on the video record. 16 WIFEREUPON, discussion was had off 17 the record. 17 THE VIDEOGRAPHER: The time is 9:52 a.m. and 18 Were back on the video record. 18 WIFERUPON, discussion was had off 18 THE VIDEOGRAPHER: The time is 9:52 a.m. and 19 Were back on the video record. 19 Were back on the video record. 10 Q. Ond can you go ahead and opou the 17 TVT-Secur' slide.) 10 Q. And can you go ahead and open that 11 device and let's talk about it briefly. 12 device and let's talk about it briefly. 13 A. Thank you. 14 Q. And can you go ahead and open that 15 device and let's talk about it briefly. 15 what is indications are, who it should not be used 16 the proper patient that it should be used on or 17 what its indications are, who it should not be used 18 on, which is contraindications. It describes the 29 adverse events and warnings associated with the 29 device. 20 Okay. 21 Devin Turber videor cord. 22 With the laser, which is end. 23 TVT-Sec		•	1	
Did you use the same methods in this case in reaching your expert conclusions as you use in your private practice? A. Yes.  Q. Are you familiar with how the TVT-Secur device is designed and how it's supposed to be placed in the human body?  A. Yes.  Q. Are you familiar with how the TVT-Secur device is designed and how it's supposed to be placed in the human body?  A. Yes.  Q. And did you help prepare a slide that illustrates the TVT-Secur device implant locations? A. Yes.  Q. And did you help prepare a slide that illustrates the TVT-Secur device implant locations? A. Yes.  Q. And would that assist, help you—help you assist the jury in understanding more about the TVT-Secur procedure?  A. Yes.  Page 39  MR. THORNBURGH:  Page 39  Page 41  MR. THORNBURGH:  Q. Doctor, I'm going to hand you the TVT-Secur device in the box that it was sold in.  A. Thank you.  Page 41  Q. And can you go ahead and open that device and let's talk about it briefly.  A. The first thing that's in the device is what's called the Instructions for Use, which we've described earlier. This contains infamications. It devices the adverse events and warnings associated with the device.  The TVT-Secur the comes out of the package. First, there are guards that are placed in two different fashions, one to resemble the into secretary device can be placed in a different fashions on to the rort position, and the other—the same device can be placed in a different fashions on it more resembles the TVT-Obturator, which is called the Lammock position.  Q. Now, Doctor, you've testified about the dates of launch of the first and second generation  The ITVT devices, the TVT Retropubic and the TVT-O, but the first and second generation  The ITVT device to the indirector of the midure thral slings.			1	
11 case in reaching your expert conclusions as you use in your private practice? 12			1	
12 In your private practice? 13 A. Yes. 14 Q. Are you familiar with how the TVT-Secur 15 device is designed and how it's supposed to be 16 placed in the human body? 17 A. Yes. 18 Q. And did you help prepare a slide that 19 illustrates the TVT-Secur device implant locations? 20 A. Yes. 21 Q. And would that assist, help you help 22 you assist the jury in understanding more about the 23 TVT-Secur procedure? 24 A. Yes. 25 Page 39 26 BR-Secur 4 the slide entitled "TVT-Secur." 27 Q. Do you recognize this document was 28 marked as BR-Secur Exhibit No. 4: 29 TVT-Secur' slide.) 40 BY MR. THORNBURGH: 51 G. Do you recognize this document? 52 G. Do you recognize this document? 53 A. Yes. 54 A. Yes. 55 G. Do you recognize this document? 56 BY MR. THORNBURGH: 57 Q. Do you recognize this document? 58 A. Yes. 59 Q. Is this the slide that you created? 50 A. It did not create the graphics, but I put it together as a slide. 51 G. Okay. 55 MR. THORNBURGH: Can we go off the record really quick. 56 THE VIDEOGRAPHER: The time is 9:52 a.m. and we are going off the video record. 57 Q. Doctor, I'm going to hand you the TVT-Secur device in the box that it was sold in. 58 A. Yes. 59 Q. Is this the slide entitled "TVT-Secur." 59 Q. Do you recognize this document? 50 A. Yes. 51 Q. Oxay. And what is the jury seeing in this screen, Doctor? 50 A. Yes. 51 Q. Oxay. And what is the jury seeing in this screen, Doctor? 51 different fashions, one to resemble the different fashions or it is called the U position, and the other the same device can be placed in a different fashion so it more resembles the TVT-Obturator, which is called the hammock position. 51 Q. Now, Doctor, you've testified about the dataset of launch of the first and second generation the TVT-Obturator, which is called the hammock position. 52 TVT devices, the TVT Retropobic and the TVT-O, but 20 dates of launch of the first and second generation and the total the TVT-O, but 20 dates of launch of the first and second generation and the TVT-O, but 20 dates of launch of the firs			1	
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14   Q. Are you familiar with how the TVT-Secur device is designed and how it's supposed to be   15		· · · · · · · · · · · · · · · · · · ·	1	
device is designed and how it's supposed to be placed in the human body?  7 A. Yes.  8 Q. And did you help prepare a slide that illustrates the TVT-Secur device implant locations?  9 A. Yes.  10 Q. And would that assist, help you help you assist the jury in understanding more about the TVT-Secur procedure?  11 Q. And would that assist, help you help you assist the jury in understanding more about the TVT-Secur procedure?  12 A. Yes.  13 WR. THORNBURGH: I will go ahead and mark as BR-Secur 4 the slide entitled "TVT-Secur."  14 (WHEREUPON, discussion was had off the record.)  15 WR. THORNBURGH: Device implant locations?  16 BY MR. THORNBURGH: I will go ahead and mark as BR-Secur 4 the slide entitled "TVT-Secur."  18 Q. And can you go ahead and open that device and let's talk about it briefly.  19 Q. And can you go ahead and open that device and let's talk about it briefly.  20 A. The first thing that's in the device is what's called the Instructions for Use, which we've described earlier. This contains information about the proper patient that it should be used on or what its indications are, who it should not be used on, which is contraindications. It describes the adverse events and warnings associated with the device.  10 A. I did not create the graphics, but I put it together as a slide.  11 it together as a slide.  12 Q. Oxa, And what is the jury seeing in this screen, Doctor?  13 different fashions, one to resemble the  14 A. Well, the TVT-Secur can be placed in two device can be placed in two device can be placed in a different fashions or it is is called the U position, and the other the same device can be placed in a different fashion so it is is called the first and second generation the hammock position.  18 A. Well, the TVT-Obturator, which is called the hammock position.  29 Q. Now, Doctor, you've testified about the davice see the mesh itself, which is tifferent fashions of the first and second generation the full-length midurethral slings.			1	
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17 A. Yes.  Q. And did you help prepare a slide that 19 illustrates the TVT-Secur device implant locations? 20 A. Yes. 21 Q. And would that assist, help you help 22 you assist the jury in understanding more about the 23 TVT-Secur procedure? 24 A. Yes. 26 Page 39 27 TVS-Secur device in the box that it was sold in. 28 A. Yes. 29 Page 41 20 And can you go ahead and you the 29 TVT-Secur device in the box that it was sold in. 29 And can you go ahead and open that 20 device and lef's talk about it briefly. 30 (WHEREUPON, a certain document was marked as BR-Secur Eshibit No. 4: 31 "TVT-Secur" slide.) 42 A. Thank you.  Page 41 43 A. The first thing that's in the device is what's called the Instructions for Use, which we've described earlier. This contains information about the proper patient that it should be used on or what its indications are, who it should not be used on, which is contraindications. It describes the advices events and warnings associated with the device. 31 TVT-Secur then comes out of the package. First, there are guards that are placed over the sharp introducer so that the implanting side that prove the sharp introducer so that the implanting side that prove the sharp introducer so that the implanting side that prove the sharp introducer so that the implanting side that prove the sharp introducer so that the implanting side that prove the sharp introducer so that the implanting side the treatment of the more resembles the TVT-Obturator, which is called the harmnock position. 4 Q. Now, Doctor, you've testified about the dates of launch of the first and second generation the dates of launch of the first and second generation the dates of launch of the first and second generation the dates of launch of the first and second generation the total care of the mesh. To be length in ideferent fashions or it is a deasory-weight, small-pore mesh, which I've described earlier. The edges are cut with the laser, which makes it stiffer and more rigid.  The length is 8 centimeters, which is different from the f			1	
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			1	
24 Could you just remind us just orienty when did the				
I I	∠4	courd you just remind us just offerry when did the	24	These are the neece ends that hold the

#### Page 42 Page 44 1 sling in place to provide support for the 1 kind of difficult with all the ends attached. I 2 midurethra. 2 don't want to take them off -- but in a U-shaped 3 3 These are the introducers, which are like this, which is very similar to the -- the 4 attached to the sharp arrowhead. These are removed 4 final position of the TVT Retropubic or out towards 5 by disengaging the introducer system so that just 5 the sides. 6 the fleece tip and the polypropylene material is 6 And this muscle here is called the 7 7 obturator internus muscle. The muscle below it is left in place. 8 Q. Other than the polypropylene material 8 called the levator ani muscle. 9 9 that you've just discussed, had the other design Q. Let me just stop you real quick. 10 characteristics of the TVT-Secur device ever been 10 A. Yes. 11 used by Ethicon or any company in the world, 11 Q. Are the obturator internus muscle and 12 12 the levator ani muscles that you just described Doctor? 13 MR. SNELL: Objection; asked and answered. 13 connected in the pelvic floor? 14 BY THE WITNESS: 14 A. Yes, they are. There is a line of 15 15 A. The length of the sling had not been connective tissue that goes between the two of 16 16 used before. The laser cutting had not been used them, which is called the arcus tendinea linea 17 17 before. The sharp arrowhead introducers had not pelvis. Above that is the obturator internus 18 been used before and the fleece tips had not been 18 muscle. Below that is the levator muscle. 19 used before. 19 The fleece tip goes out towards this 20 20 BY MR. THORNBURGH: obturator internus muscle but does not actually 21 21 Q. Now, would it assist you in describing puncture that obturator internus muscle. 22 the procedure and the device to look at a pelvic 22 However, this structure right here is 23 model? 23 called the urogenital diaphragm, and that is 24 A. Yes. 24 actually pierced when this is going into the U Page 43 Page 45 Q. Going to hand you a female pelvic model. 1 1 position to sit right behind the pubic bone. 2 A. Thank you. 2 Q. Okay. And if you turn the model around 3 3 Q. Can you just describe to the ladies and at the front, where does, on the front view, where 4 gentlemen of the jury briefly what you're showing does the -- can you show the ladies and gentlemen 5 5 and what you have in your hands. of the jury where the Secur device is implanted 6 6 using the U and the H? A. Well, this is what's described as the 7 7 bony pelvis, and these are what are called the A. So --8 8 wings of or the iliac crest. This is the pubic Q. By "H," I mean the hammock approach. 9 bone. These are the pubic rami. These are 9 A. It's difficult with this. But the U 10 10 would be going in and up and would stay behind the actually the bones that we sit on. 11 Inside we have the uterus, the bladder 11 pubic bone. The H, it would go in and out and 12 12 would go out towards the obturator internus muscle. and way back here is the rectum. We are going to 13 kind of take this out for the points or the -- for 13 Q. Now, you -- sorry. 14 the rest of our discussion about how the TVT-Secur 14 You had discussed the IFU or the 15 device is placed. 15 Information for Use and you showed that to the 16 Looking -- these would represent the 16 jury. Can you show them that again, please? 17 17 lips of the vagina. This is the opening of the A. Yes. 18 vagina. And this would be the urethral opening 18 O. Okay. And does the TVT-Secur IFU or 19 right here. 19 Information for Use, does that come included in 20 So, the TVT-Secur device is placed in 20 every box that is shipped to a doctor? 21 21 through a small incision made inside the vagina A. Yes. 22 underneath the urethra and then if we look from 22 MR. SNELL: Objection. Hold on. Objection; 23 this angle, when it's in place, it can either be 23 foundation, ship to doctor. Go ahead. 24 in -- around the urethra in a U-shaped, and it's 24 BY THE WITNESS:

	Page 46		Page 48
1	A. It's shipped to the hospital.	1	MR. SNELL: Object; leading. Go ahead.
2	BY MR. THORNBURGH:	2	BY THE WITNESS:
3	Q. Shipped to the hospital. So, is it	3	A. Yes, I have.
4	included is the TVT IFU booklet included within	4	BY MR. THORNBURGH:
5	the box that is shipped to every hospital?	5	Q. Did you review any other materials
6	A. Yes. To be used by the doctor in the	6	concerning the implantation of the TVT-Secur
7	operating room.	7	device?
8	Q. And does it stay with the TVT-Secur	8	A. Yes, I reviewed a training video.
9	product until the doctor opens the TVT-Secur box?	9	Q. And would it help you in explaining the
10	MR. SNELL: Object; foundation.	10	procedure and the device if we viewed the TVT-Secur
11	BY THE WITNESS:	11	implant training video?
12	A. Correct.	12	A. Yes.
13	BY MR. THORNBURGH:	13	MR. SNELL: Object; leading. Go ahead.
14	Q. In your experience with the TVT devices,	14	BY THE WITNESS:
15	family of devices, you've implanted some of the	15	A. Yes, I think that it would be important
16	full-length devices, correct?	16	for the jury to be able to understand how the
17	A. Correct, as I've testified to	17	device is implanted to be able to see the video.
18	previously.	18	MR. THORNBURGH: And let's go ahead and play
19	Q. And did the did the IFUs or	19	the video. It's Exhibit P1801. But before we do
20	Information for Use related to those devices, were	20	that, I'm going to ask
21	those included in the boxes that came from Ethicon?	21	MR. SNELL: 1801.
22	A. Yes.	22	MR. THORNBURGH: 1801. If the videographer
23	Q. Did Ethicon ever attach, to your	23	could turn the camera and zoom in on the screen so
24	knowledge, based on your review of the internal	24	that we can view this on video.
	knowledge, subset on your review of the internal		
	Page 47		Page 49
1	documents and your experience, did they ever attach	1	THE VIDEOGRAPHER: I just need a moment to
2	any other warnings or instructions other than the	2	focus.
3	IFU to the to the boxes?	3	MR. THORNBURGH: No problem.
4	MR. SNELL: Object; leading. Go ahead.	4	MR. SNELL: Perfect. While you're doing that,
5	BY THE WITNESS:	5	I will put an objection on the record.
6	A. Not that is not contained in the	6	I will object to the showing of the
7	Instructions for Use.	7	video to the jury for the reasons articulated in
8	BY MR. THORNBURGH:	8	previous trials, including the TVT-Secur trial,
9	Q. So, is there any other instruction or	9	wherein, one, it's overly graphic and it's not the
10	warnings that come with these products other than	10	type of material that's intended to be viewed by
11	the IFU?	11	the layperson.
12	A. No.	12	These are, as I believe the witness
13	MR. SNELL: Objection; overbroad now.	13	testified, part of the professional education
14	BY THE WITNESS:	14	training program for doctors. So they're intended
15	A. No.	15	for doctors. A jury
16	BY MR. THORNBURGH:	16	MR. THORNBURGH: Can I just say I'm sorry.
17	Q. And we are going to talk about the	17	MR. SNELL: No.
18	Information for Use and labeling and warnings	18	MR. THORNBURGH: I think the rules say you can
19	throughout today. Okay?	19	object. But no speaking objections. I understand
20	A. Yes.	20	what you're doing. We understand your position.
21	Q. Now, Doctor, in coming here today and in	21	MR. SNELL: I'm laying the foundation.
	forming your opinions, have you also reviewed a	22	MR. THORNBURGH: I'm not saying you are
22		""	The file of the first state of t
22 23	training video produced by Ethicon on how to	23	waiving your objections. Linet want to be able to
22 23 24	training video produced by Ethicon on how to implant a TVT-Secur in a woman's vagina?	23 24	waiving your objections. I just want to be able to move on and get through this.

	Page 50		Page 52
1	MR. SNELL: As long as you are saying I am not	1	MR. THORNBURGH: Just say "Objection" and we
2	waiving it. I was just stating the bases.	2	can deal with it later on with the judge.
3	MR. THORNBURGH: I know. I don't think that's	3	MR. SNELL: The problem is I know the bases
4	appropriate in either Federal Court or	4	that I'm prepared to assert under Pennsylvania law
5	Pennsylvania.	5	right here and now, and I want to make sure they're
6	MR. SNELL: Oh, no, it is, because if this	6	on the record as opposed to somebody else trying to
7	was this is a trial deposition. If we were	7	figure out what I was objecting to.
8	before the judge, I'd ask for a sidebar and I'd	8	MR. THORNBURGH: We have done this time and
9	make this record right now. But you're saying if	9	time again on videos. We just object and we deal
10	I'm not waiving it	10	with the objections later on. We have this
11	MR. THORNBURGH: Note the objection but you're	11	agreement, the stipulation in every case.
12	not waiving it if you don't give the basis for your	12	MR. SNELL: Actually, we didn't. If you had
13	objection on this video. Okay?	13	read the Carlino TVT deposition, you saw Mr. Freese
14	MR. SNELL: Okay.	14	and I both provided our objections.
15	MR. THORNBURGH: All right.	15	MR. THORNBURGH: Okay. I will just I will
16	BY MR. THORNBURGH:	16	provide long speaking objections on your cross. If
17	Q. Okay. So, now, is this the video that	17	we're not going to reach an agreement, that's what
18	you review and rely upon in part in formulating	18	I'll do too.
19	your opinions in this case?	19	MR. SNELL: Okay. You can do whatever you
20	A. Yes.	20	want to do.
21	Q. Now, you testified that one of the	21	BY MR. THORNBURGH:
22	things that were provided to you when you were	22	Q. Doctor, based based on your
23	first introduced to the TVT-Secur product was a	23	discussion and your introduction to the TVT-Secur
24	promotional piece?	24	device, what was your understanding of the implant
	Page 51		Page 53
1	A. Correct.	1	technique?
2	Q. And we're going to look at a lot of	2	A. That it was easy to use and minimally
3	documents throughout today. But what did Ethicon	3	invasive.
4	represent to doctors concerning the ease of	4	Q. And based on your review of the internal
5	implantation of the TVT-Secur device.	5	documents strike that.
6	MR. SNELL: Object to the preface. Objection;	6	Do you have an opinion whether or not
7	improper subject matter as to what Ethicon	7	those representations were accurate?
8	represented. This is not an expert on state of	8	A. I do have an opinion.
9	mind.		O WH
		9	Q. What is that opinion, Doctor?
10	Secondly, this is the material that the	10	A. They are not accurate.
10 11	Secondly, this is the material that the jury	10 11	<ul><li>A. They are not accurate.</li><li>Q. And what's the basis for that opinion,</li></ul>
10 11 12	Secondly, this is the material that the jury BY MR. THORNBURGH:	10 11 12	<ul><li>A. They are not accurate.</li><li>Q. And what's the basis for that opinion,</li><li>Doctor?</li></ul>
10 11 12 13	Secondly, this is the material that the jury BY MR. THORNBURGH: Q. What was your understanding	10 11 12 13	<ul><li>A. They are not accurate.</li><li>Q. And what's the basis for that opinion,</li><li>Doctor?</li><li>A. The internal documents that I reviewed,</li></ul>
10 11 12 13 14	Secondly, this is the material that the jury BY MR. THORNBURGH: Q. What was your understanding MR. SNELL: can consider for themselves.	10 11 12 13 14	<ul> <li>A. They are not accurate.</li> <li>Q. And what's the basis for that opinion,</li> <li>Doctor?</li> <li>A. The internal documents that I reviewed,</li> <li>the training videos that I've looked at and also</li> </ul>
10 11 12 13 14 15	Secondly, this is the material that the jury BY MR. THORNBURGH: Q. What was your understanding MR. SNELL: can consider for themselves. MR. THORNBURGH: Okay. So, you're going to	10 11 12 13 14 15	<ul> <li>A. They are not accurate.</li> <li>Q. And what's the basis for that opinion,</li> <li>Doctor?</li> <li>A. The internal documents that I reviewed,</li> <li>the training videos that I've looked at and also</li> <li>the deposition testimony.</li> </ul>
10 11 12 13 14 15 16	Secondly, this is the material that the jury BY MR. THORNBURGH: Q. What was your understanding MR. SNELL: can consider for themselves. MR. THORNBURGH: Okay. So, you're going to give speaking objections rather than just object	10 11 12 13 14 15 16	<ul> <li>A. They are not accurate.</li> <li>Q. And what's the basis for that opinion,</li> <li>Doctor?</li> <li>A. The internal documents that I reviewed,</li> <li>the training videos that I've looked at and also</li> <li>the deposition testimony.</li> <li>Q. Okay.</li> </ul>
10 11 12 13 14 15 16	Secondly, this is the material that the jury BY MR. THORNBURGH: Q. What was your understanding MR. SNELL: can consider for themselves. MR. THORNBURGH: Okay. So, you're going to give speaking objections rather than just object and handle them later on?	10 11 12 13 14 15 16 17	<ul> <li>A. They are not accurate.</li> <li>Q. And what's the basis for that opinion,</li> <li>Doctor?</li> <li>A. The internal documents that I reviewed,</li> <li>the training videos that I've looked at and also</li> <li>the deposition testimony.</li> <li>Q. Okay.</li> <li>MR. THORNBURGH: Tom, can you go ahead and hit</li> </ul>
10 11 12 13 14 15 16 17	Secondly, this is the material that the jury BY MR. THORNBURGH: Q. What was your understanding MR. SNELL: can consider for themselves. MR. THORNBURGH: Okay. So, you're going to give speaking objections rather than just object and handle them later on? I'm just trying to get through the day	10 11 12 13 14 15 16 17	<ul> <li>A. They are not accurate.</li> <li>Q. And what's the basis for that opinion,</li> <li>Doctor?</li> <li>A. The internal documents that I reviewed,</li> <li>the training videos that I've looked at and also</li> <li>the deposition testimony.</li> <li>Q. Okay.</li> <li>MR. THORNBURGH: Tom, can you go ahead and hit play.</li> </ul>
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	Page 54		Page 56
1	at the level of the midurethra. It is made	1	BY MR. THORNBURGH:
2	approximately 1 centimeter below the opening of the	2	Q. And, so, we are that's it. We're
3	urethra and a cut is made down in through a full	3	good there.
4	thickness passage through both the vaginal	4	Now, the introducers, they don't get
5	epithelium, the subepithelial tissue into a plane	5	left in the device in the body permanently?
6	that is a full thickness below the vagina and	6	A. No, they do not.
7	before you actually hit the urethral tissue or the	7	Q. Okay. Does the Prolene polypropylene
8	bladder tissue in a level called the deep	8	mesh and fleece mesh remain in the body strike
9	endopelvic fascia.	9	that.
10	MR. THORNBURGH: Go ahead, Tom.	10	Is the TVT-Secur Prolene polypropylene
11	BY THE WITNESS:	11	mesh material supposed to be left permanently
12	A. At this point the surgeon is using	12	inside the human body?
13	scissors to create a tunnel. Here the sharp	13	A. Yes.
14	arrowhead introducer is being placed into the	14	Q. And was the Secur meant to be a
15	tunnel path that has been created.	15	permanently implanted medical device?
16	It is being pushed out towards the side.	16	A. Yes.
17	This is representing the hammock approach or the H	17	THE VIDEOGRAPHER: Excuse me, counselor. I
18	approach. And the surgeon is pushing the	18	can I can photograph capture other exhibits that
19	introducer system with the arrowhead on the end out	19	you have on screen if you want them.
20	towards the obturator internus muscle.	20	MR. THORNBURGH: Okay.
21	BY MR. THORNBURGH:	21	THE VIDEOGRAPHER: You can just let me know.
22	Q. So, is the doctor who is implanting this	22	MR. THORNBURGH: Okay. Thank you. Appreciate
23	device pushing the sharp arrowhead introducers	23	that.
24	through the tissue?	24	MR. SNELL: I think we have an agreement that
21	though the tissue.		That D. (222) I dilline we have all agreement dime
	Page 55		Page 57
1	A. Yes.	1	we can put them up when the witness is testifying.
2	Q. And through muscle?	2	That's what Rich Mr. Freese and I agreed in
3	A. No, not through muscle. Actually, it's	3	Carlino.
4	going out towards the muscle of the obturator	4	MR. THORNBURGH: We are going to put them up
5	internus muscle.	5	live at trial.
6	Q. Okay.	6	MR. SNELL: Exactly.
7	A. This is when both sides are placed.	7	MR. THORNBURGH: Yeah, that's right.
8	Now, the introducer system is going to	8	MR. SNELL: Okay.
9	be removed.	9	BY MR. THORNBURGH:
10	Right now the doctor is tensioning the	10	Q. Now, Dr. Rosenzweig, when you treated
11	or attempting to tension the TVT-Secur device at	11	the your patients with complications from the
12	the level of the midurethra.	1 1 2	TVT-Secur device, did you ever have to surgically
	the level of the initiatrethra.	12	1 v 1-sectif device, did you ever have to surgically
13	Q. We're going to talk about tensioning	13	remove the Secur device?
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13 14	Q. We're going to talk about tensioning throughout today.	13 14	remove the Secur device?  MR. SNELL: Object; asked and answered,
13 14 15	<ul><li>Q. We're going to talk about tensioning throughout today.</li><li>MR. SNELL: Object to counsel's statement. Go</li></ul>	13 14 15	remove the Secur device?  MR. SNELL: Object; asked and answered, repetition.
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13 14 15 16 17 18	Q. We're going to talk about tensioning throughout today.  MR. SNELL: Object to counsel's statement. Go ahead.  BY THE WITNESS:  A. At this point the device is being placed	13 14 15 16 17 18	remove the Secur device?  MR. SNELL: Object; asked and answered, repetition.  BY THE WITNESS:  A. Yes, I did.  BY MR. THORNBURGH:  Q. Does the removal of a mesh or TVT-Secur
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15 (Pages 54 to 57)

	Page 58		Page 60
1	A. No, it does not.	1	Q. Doctor, do you have an opinion
2	BY MR. THORNBURGH:	2	Doctor, what are your opinions about the TVT-Secur
3	Q. Even when you remove all the mesh?	3	device?
4	A. Yes.	4	MR. SNELL: Objection; repetition.
5	Q. Why is that?	5	BY THE WITNESS:
6	A. As I have described earlier, there is	6	A. I have already outlined my opinions
7	often scarring that takes place due to the chronic	7	about the TVT-Secur device.
8	foreign body reaction, chronic inflammatory	8	BY MR. THORNBURGH:
9	reaction, scar that grows around the mesh that is	9	Q. And what is the basis for those
10	left behind.	10	opinions?
11	There are nerves that grow through the	11	A. One of the bases for those opinions are
12	mesh that are injured as the mesh undergoes the	12	the internal Ethicon documents.
13	contraction process that I've described previously.	13	Q. And did you bring some of those
14	Those nerves are permanently injured. And, so, the	14	documents with you today?
15	removal of a piece or all of the mesh device does	15	A. Yes, I did.
16	not always treat pain, pain with intercourse,	16	Q. And are those in front of you?
17	difficulty voiding, which are the common	17	A. Yes, they are.
18	indications for removing the device as I've	18	Q. And would those assist the jury in
19	testified to earlier.	19	understanding your opinions in this case?
20	And it's supported in the literature	20	A. Yes.
21	that even with complete removal of the device,	21	MR. SNELL: Object; leading.
22	those indications for removing the devices, those	22	BY MR. THORNBURGH:
23	complications are not always resolved.	23	Q. What is the first internal company
24	Q. Now, at this point, Doctor, I'd like to	24	document that you'd like to discuss with the jury
	2 50		
	Page 59		Page 61
1	discuss some of Ethicon's internal company	1	today?
2	discuss some of Ethicon's internal company documents that you reviewed and relied upon in	2	today?  MR. SNELL: Object; leading, improper
2	discuss some of Ethicon's internal company documents that you reviewed and relied upon in forming your opinions in this case. Okay?	2 3	today?  MR. SNELL: Object; leading, improper Pennsylvania procedure.
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16 (Pages 58 to 61)

	Page 62		Page 64
1	including Dr. Brigitte Hellhammer.	1	Do you see that?
2	Q. And how is this document significant to	2	A. Yes.
3	your opinions?	3	Q. And it's from Brigitte Hellhammer sent
4	A. This document is significant to my	4	to an Ethicon employee, a Ms. Waljii and cc'd to
5	opinions as it describes that Ethicon employees did	5	Dr. Engel Dieter.
6	not envision ever needing to remove the TVT or	6	Do you see that?
7	the Prolene mesh after it was placed in the human	7	A. Yes.
8	body, first, as an embodiment of the	8	Q. And it says, "Dear Zenobia," and this is
9	TVT Retropubic. Obviously this predates the	9	Brigitte Hellhammer writing. "Dear Zenobia.
10	TVT-Secur.	10	During his recent visit with us, Professor Klutke
11	Q. Okay.	11	explained a simple technique to use how to explant
12	MR. SNELL: Object. Move to strike.	12	a Prolene mesh tape, namely by using a normal
13	Improper improper state of mind opinion as to	13	electrocautery device with cutting (not
14	what Ethicon people thought.	14	coagulating) current."
15	BY MR. THORNBURGH:	15	Do you see that?
16	Q. What was your understanding when you	16	A. Yes.
17	read this document concerning the removal of the	17	Q. It goes on to say, "The procedure is
18	TVT device and and publications concerning the	18	dissect the tape free is simple and quick according
19	removal of the TVT device?	19	to Professor Klutke. Although the necessity to
20	MR. SNELL: Object; vague.	20	dissect the tape is extremely rare, this particular
21	BY THE WITNESS:	21	procedure is interesting, as in early conversation
22	A. Well, this is regarding a doctor who is	22	with gynecologic surgeons, they told me that
23	going to be writing a paper about needing to remove	23	dissection would be tedious and requires long
24	the entire TVT device. Ms. Angelini states, "I do	24	operation time."
	Page 63		Page 65
1	not envision any need to explant the TVT."	1	Did I read that correctly?
2	BY MR. THORNBURGH:	2	A. Yes.
3	Q. Based on your knowledge, training and	3	Q. Okay. And if you what is your
4	experience, your review of materials that you	4	understanding of what was occurring here in 2002
5	testified you reviewed in this case, is it correct	5	concerning what Professor Klutke was working on?
6	that there would not be a need, a clinical a	6	MR. SNELL: Objection; vague.
_	medical clinical need for the removal of a TVT	7	
7		1 '	BY THE WITNESS:
8	Prolene polypropylene sling device?	8	BY THE WITNESS:  A. What Dr. Klutke is describing is a
	Prolene polypropylene sling device?  MR. SNELL: Object; leading.		
8		8	A. What Dr. Klutke is describing is a
8 9	MR. SNELL: Object; leading.	8 9	A. What Dr. Klutke is describing is a technique for being able to remove the mesh that he
8 9 10	MR. SNELL: Object; leading. BY THE WITNESS:	8 9 10	A. What Dr. Klutke is describing is a technique for being able to remove the mesh that he felt would be much quicker and easier, both using
8 9 10 11	MR. SNELL: Object; leading. BY THE WITNESS: A. No.	8 9 10 11	A. What Dr. Klutke is describing is a technique for being able to remove the mesh that he felt would be much quicker and easier, both using electrocautery, which is an energy system which not
8 9 10 11 12	MR. SNELL: Object; leading. BY THE WITNESS: A. No. BY MR. THORNBURGH:	8 9 10 11 12	A. What Dr. Klutke is describing is a technique for being able to remove the mesh that he felt would be much quicker and easier, both using electrocautery, which is an energy system which not only can cut tissue but seal blood vessels, and
8 9 10 11 12 13	MR. SNELL: Object; leading. BY THE WITNESS: A. No. BY MR. THORNBURGH: Q. And who is Dr. Klutke?	8 9 10 11 12 13	A. What Dr. Klutke is describing is a technique for being able to remove the mesh that he felt would be much quicker and easier, both using electrocautery, which is an energy system which not only can cut tissue but seal blood vessels, and cutting.
8 9 10 11 12 13 14	MR. SNELL: Object; leading. BY THE WITNESS: A. No. BY MR. THORNBURGH: Q. And who is Dr. Klutke? A. Dr. Klutke is a urogynecologist, a	8 9 10 11 12 13 14	A. What Dr. Klutke is describing is a technique for being able to remove the mesh that he felt would be much quicker and easier, both using electrocautery, which is an energy system which not only can cut tissue but seal blood vessels, and cutting.  Q. Now, if you turn to the next e-mail in
8 9 10 11 12 13 14 15	MR. SNELL: Object; leading. BY THE WITNESS: A. No. BY MR. THORNBURGH: Q. And who is Dr. Klutke? A. Dr. Klutke is a urogynecologist, a well-known pelvic surgeon.	8 9 10 11 12 13 14 15	A. What Dr. Klutke is describing is a technique for being able to remove the mesh that he felt would be much quicker and easier, both using electrocautery, which is an energy system which not only can cut tissue but seal blood vessels, and cutting.  Q. Now, if you turn to the next e-mail in this exhibit, Dr there is a Zenobia Waljii.
8 9 10 11 12 13 14 15	MR. SNELL: Object; leading. BY THE WITNESS: A. No. BY MR. THORNBURGH: Q. And who is Dr. Klutke? A. Dr. Klutke is a urogynecologist, a well-known pelvic surgeon. Q. And Dr. Brigitte Hellhammer. Do you	8 9 10 11 12 13 14 15	A. What Dr. Klutke is describing is a technique for being able to remove the mesh that he felt would be much quicker and easier, both using electrocautery, which is an energy system which not only can cut tissue but seal blood vessels, and cutting.  Q. Now, if you turn to the next e-mail in this exhibit, Dr there is a Zenobia Waljii.  Do you see that?
8 9 10 11 12 13 14 15 16	MR. SNELL: Object; leading. BY THE WITNESS: A. No. BY MR. THORNBURGH: Q. And who is Dr. Klutke? A. Dr. Klutke is a urogynecologist, a well-known pelvic surgeon. Q. And Dr. Brigitte Hellhammer. Do you know who she is?	8 9 10 11 12 13 14 15 16	A. What Dr. Klutke is describing is a technique for being able to remove the mesh that he felt would be much quicker and easier, both using electrocautery, which is an energy system which not only can cut tissue but seal blood vessels, and cutting.  Q. Now, if you turn to the next e-mail in this exhibit, Dr there is a Zenobia Waljii.  Do you see that?  A. Yes.
8 9 10 11 12 13 14 15 16 17	MR. SNELL: Object; leading. BY THE WITNESS: A. No. BY MR. THORNBURGH: Q. And who is Dr. Klutke? A. Dr. Klutke is a urogynecologist, a well-known pelvic surgeon. Q. And Dr. Brigitte Hellhammer. Do you know who she is? A. Yes. She is a scientist at Ethicon.	8 9 10 11 12 13 14 15 16 17	A. What Dr. Klutke is describing is a technique for being able to remove the mesh that he felt would be much quicker and easier, both using electrocautery, which is an energy system which not only can cut tissue but seal blood vessels, and cutting.  Q. Now, if you turn to the next e-mail in this exhibit, Dr there is a Zenobia Waljii.  Do you see that?  A. Yes.  Q. Who responds to Brigitte Hellhammer and
8 9 10 11 12 13 14 15 16 17 18	MR. SNELL: Object; leading. BY THE WITNESS: A. No. BY MR. THORNBURGH: Q. And who is Dr. Klutke? A. Dr. Klutke is a urogynecologist, a well-known pelvic surgeon. Q. And Dr. Brigitte Hellhammer. Do you know who she is? A. Yes. She is a scientist at Ethicon. Q. And who is Ms. Angelini?	8 9 10 11 12 13 14 15 16 17 18	A. What Dr. Klutke is describing is a technique for being able to remove the mesh that he felt would be much quicker and easier, both using electrocautery, which is an energy system which not only can cut tissue but seal blood vessels, and cutting.  Q. Now, if you turn to the next e-mail in this exhibit, Dr there is a Zenobia Waljii.  Do you see that?  A. Yes.  Q. Who responds to Brigitte Hellhammer and she writes, "Dear Briggite, Thanks for your
8 9 10 11 12 13 14 15 16 17 18 19 20	MR. SNELL: Object; leading. BY THE WITNESS: A. No. BY MR. THORNBURGH: Q. And who is Dr. Klutke? A. Dr. Klutke is a urogynecologist, a well-known pelvic surgeon. Q. And Dr. Brigitte Hellhammer. Do you know who she is? A. Yes. She is a scientist at Ethicon. Q. And who is Ms. Angelini? A. She's in marketing.	8 9 10 11 12 13 14 15 16 17 18 19 20	A. What Dr. Klutke is describing is a technique for being able to remove the mesh that he felt would be much quicker and easier, both using electrocautery, which is an energy system which not only can cut tissue but seal blood vessels, and cutting.  Q. Now, if you turn to the next e-mail in this exhibit, Dr there is a Zenobia Waljii.  Do you see that?  A. Yes.  Q. Who responds to Brigitte Hellhammer and she writes, "Dear Briggite, Thanks for your thoughts below. In principle I am comfortable with
8 9 10 11 12 13 14 15 16 17 18 19 20 21	MR. SNELL: Object; leading. BY THE WITNESS: A. No. BY MR. THORNBURGH: Q. And who is Dr. Klutke? A. Dr. Klutke is a urogynecologist, a well-known pelvic surgeon. Q. And Dr. Brigitte Hellhammer. Do you know who she is? A. Yes. She is a scientist at Ethicon. Q. And who is Ms. Angelini? A. She's in marketing. Q. If you turn with me to Exhibit 1553, the	8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. What Dr. Klutke is describing is a technique for being able to remove the mesh that he felt would be much quicker and easier, both using electrocautery, which is an energy system which not only can cut tissue but seal blood vessels, and cutting.  Q. Now, if you turn to the next e-mail in this exhibit, Dr there is a Zenobia Waljii.  Do you see that?  A. Yes.  Q. Who responds to Brigitte Hellhammer and she writes, "Dear Briggite, Thanks for your thoughts below. In principle I am comfortable with you contacting any of the US clinicians. However,
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MR. SNELL: Object; leading. BY THE WITNESS: A. No. BY MR. THORNBURGH: Q. And who is Dr. Klutke? A. Dr. Klutke is a urogynecologist, a well-known pelvic surgeon. Q. And Dr. Brigitte Hellhammer. Do you know who she is? A. Yes. She is a scientist at Ethicon. Q. And who is Ms. Angelini? A. She's in marketing. Q. If you turn with me to Exhibit 1553, the first e-mail from Brigite Hellhammer at the bottom	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. What Dr. Klutke is describing is a technique for being able to remove the mesh that he felt would be much quicker and easier, both using electrocautery, which is an energy system which not only can cut tissue but seal blood vessels, and cutting.  Q. Now, if you turn to the next e-mail in this exhibit, Dr there is a Zenobia Waljii.  Do you see that?  A. Yes.  Q. Who responds to Brigitte Hellhammer and she writes, "Dear Briggite, Thanks for your thoughts below. In principle I am comfortable with you contacting any of the US clinicians. However, before you do so, I would really like to understand

	Page 66		Page 68
1	Do you see that?	1	decide on whether or not they will use a specific
2	A. Yes.	2	product.
3	Q. Is it ever okay for in your opinion,	3	Q. And how did if you look at
4	is it ever okay do you have an opinion one way	4	Exhibit 1553, how did Laura Angelini respond to the
5	or the other whether it's okay for medical device	5	possibility of Dr. Klutke publishing his technique
6	manufacturers of permanently implantable devices to	6	for the removal of TVT midurethral sling?
7	withhold a publication because the publication	7	MR. SNELL: Object. Reading e-mails by an
8	could cause a repercussion or consequences to the	8	expert, improper subject matter. Jury can read the
9	bottom line of the financial stability of the	9	e-mail themselves.
10	product?	10	BY THE WITNESS:
11	MR. SNELL: Object; improper subject matter.	11	A. She states, "Frankly, I do not want to
12	That opinion that you're seeking to elicit is not	12	dig my own grave."
13	explicitly in his Pennsylvania report.	13	Q. How is that, if at all, significant to
14	MR. THORNBURGH: Let me ask a better way.	14	your opinions, Doctor?
15	MR. SNELL: Secondly	15	A. It's significant to my opinions in that
16	MR. THORNBURGH: I'm going to withdraw it. I	16	a medical device company should want all the
17	withdraw the question.	17	information, both the good information that
18	MR. SNELL: Secondly, I object to you reading	18	supports their product plus also the bad
19	e-mails. That's not how you examine on direct an	19	information that might not support their product or
20	expert in Pennsylvania.	20	does not support their product, to be known by
21	MR. THORNBURGH: I'm going to withdraw the	21	doctors so doctors can make informed decisions
22	last question. Let me restate it.	22	about the use of a product to be able to give that
23	BY MR. THORNBURGH:	23	information to patients.
24	Q. Doctor, do you have an opinion whether	24	Q. Is Laura Angelini a medical doctor?
	Page 67		Page 69
1	companies such as Ethicon and Johnson & Johnson	1	A. No.
2	should put patient safety before profit?	2	MR. SNELL: Object; asked and answered.
3	A. Yes.	3	Covered earlier.
4	Q. Why is that?	4	BY MR. THORNBURGH:
_		_	
5	<ol> <li>Because patient safety is paramount.</li> </ol>	5	Q. What is Laura what was Laura
5 6	<ul><li>A. Because patient safety is paramount.</li><li>Q. And do you have an opinion whether or</li></ul>		
		5	<ul><li>Q. What is Laura what was Laura</li><li>Angelini's position at Ethicon?</li><li>MR. SNELL: Objection; covered earlier. Go</li></ul>
6	Q. And do you have an opinion whether or	5 6	Angelini's position at Ethicon?
6 7	Q. And do you have an opinion whether or not companies like Ethicon and Johnson & Johnson	5 6 7	Angelini's position at Ethicon?  MR. SNELL: Objection; covered earlier. Go
6 7 8	Q. And do you have an opinion whether or not companies like Ethicon and Johnson & Johnson should disclose the good, the bad and the ugly	5 6 7 8	Angelini's position at Ethicon?  MR. SNELL: Objection; covered earlier. Go ahead.
6 7 8 9	Q. And do you have an opinion whether or not companies like Ethicon and Johnson & Johnson should disclose the good, the bad and the ugly concerning products it's selling as permanent	5 6 7 8 9	Angelini's position at Ethicon?  MR. SNELL: Objection; covered earlier. Go ahead.  BY THE WITNESS:
6 7 8 9 10	Q. And do you have an opinion whether or not companies like Ethicon and Johnson & Johnson should disclose the good, the bad and the ugly concerning products it's selling as permanent implantable devices?	5 6 7 8 9	Angelini's position at Ethicon?  MR. SNELL: Objection; covered earlier. Go ahead.  BY THE WITNESS:  A. Marketing.
6 7 8 9 10 11	Q. And do you have an opinion whether or not companies like Ethicon and Johnson & Johnson should disclose the good, the bad and the ugly concerning products it's selling as permanent implantable devices?  MR. SNELL: Objection; argumentative, outside	5 6 7 8 9 10 11	Angelini's position at Ethicon?  MR. SNELL: Objection; covered earlier. Go ahead.  BY THE WITNESS:  A. Marketing.  BY MR. THORNBURGH:
6 7 8 9 10 11	Q. And do you have an opinion whether or not companies like Ethicon and Johnson & Johnson should disclose the good, the bad and the ugly concerning products it's selling as permanent implantable devices?  MR. SNELL: Objection; argumentative, outside the scope of his expert report as well now.	5 6 7 8 9 10 11 12	Angelini's position at Ethicon?  MR. SNELL: Objection; covered earlier. Go ahead.  BY THE WITNESS:  A. Marketing.  BY MR. THORNBURGH:  Q. So, are you telling the ladies and
6 7 8 9 10 11 12	Q. And do you have an opinion whether or not companies like Ethicon and Johnson & Johnson should disclose the good, the bad and the ugly concerning products it's selling as permanent implantable devices?  MR. SNELL: Objection; argumentative, outside the scope of his expert report as well now. BY THE WITNESS:	5 6 7 8 9 10 11 12 13	Angelini's position at Ethicon?  MR. SNELL: Objection; covered earlier. Go ahead.  BY THE WITNESS:  A. Marketing.  BY MR. THORNBURGH:  Q. So, are you telling the ladies and gentlemen of the jury that Laura Angelini, a marketing person, is concerned about providing safety information to physicians?
6 7 8 9 10 11 12 13	Q. And do you have an opinion whether or not companies like Ethicon and Johnson & Johnson should disclose the good, the bad and the ugly concerning products it's selling as permanent implantable devices?  MR. SNELL: Objection; argumentative, outside the scope of his expert report as well now.  BY THE WITNESS:  A. Yes, I have an opinion.	5 6 7 8 9 10 11 12 13 14	Angelini's position at Ethicon?  MR. SNELL: Objection; covered earlier. Go ahead.  BY THE WITNESS:  A. Marketing.  BY MR. THORNBURGH:  Q. So, are you telling the ladies and gentlemen of the jury that Laura Angelini, a marketing person, is concerned about providing
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6 7 8 9 10 11 12 13 14 15 16 17	Q. And do you have an opinion whether or not companies like Ethicon and Johnson & Johnson should disclose the good, the bad and the ugly concerning products it's selling as permanent implantable devices?  MR. SNELL: Objection; argumentative, outside the scope of his expert report as well now. BY THE WITNESS:  A. Yes, I have an opinion. BY MR. THORNBURGH: Q. What's that opinion? MR. SNELL: This is a jury question too. Go	5 6 7 8 9 10 11 12 13 14 15 16	Angelini's position at Ethicon?  MR. SNELL: Objection; covered earlier. Go ahead.  BY THE WITNESS:  A. Marketing.  BY MR. THORNBURGH:  Q. So, are you telling the ladies and gentlemen of the jury that Laura Angelini, a marketing person, is concerned about providing safety information to physicians?  MR. SNELL: Objection; improper state of mind. This is outside the scope of his report too. He
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6 7 8 9 10 11 12 13 14 15 16 17 18	Q. And do you have an opinion whether or not companies like Ethicon and Johnson & Johnson should disclose the good, the bad and the ugly concerning products it's selling as permanent implantable devices?  MR. SNELL: Objection; argumentative, outside the scope of his expert report as well now. BY THE WITNESS:  A. Yes, I have an opinion. BY MR. THORNBURGH: Q. What's that opinion? MR. SNELL: This is a jury question too. Go ahead. BY THE WITNESS:	5 6 7 8 9 10 11 12 13 14 15 16 17 18	Angelini's position at Ethicon?  MR. SNELL: Objection; covered earlier. Go ahead.  BY THE WITNESS:  A. Marketing.  BY MR. THORNBURGH:  Q. So, are you telling the ladies and gentlemen of the jury that Laura Angelini, a marketing person, is concerned about providing safety information to physicians?  MR. SNELL: Objection; improper state of mind. This is outside the scope of his report too. He does not  MR. THORNBURGH: Just object. Just object.
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. And do you have an opinion whether or not companies like Ethicon and Johnson & Johnson should disclose the good, the bad and the ugly concerning products it's selling as permanent implantable devices?  MR. SNELL: Objection; argumentative, outside the scope of his expert report as well now. BY THE WITNESS:  A. Yes, I have an opinion. BY MR. THORNBURGH: Q. What's that opinion? MR. SNELL: This is a jury question too. Go ahead. BY THE WITNESS: A. Yes, they should.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Angelini's position at Ethicon?  MR. SNELL: Objection; covered earlier. Go ahead.  BY THE WITNESS:  A. Marketing.  BY MR. THORNBURGH:  Q. So, are you telling the ladies and gentlemen of the jury that Laura Angelini, a marketing person, is concerned about providing safety information to physicians?  MR. SNELL: Objection; improper state of mind. This is outside the scope of his report too. He does not  MR. THORNBURGH: Just object. Just object.  MR. SNELL: No, I'm not. I am giving a proper
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18 (Pages 66 to 69)

	Page 70		Page 72
1	Court's Judge Greenspan's telephone number? We	1	it's appropriate for a person in marketing to
2	are going to call if we have to. We've done this	2	control the information being published to
3	before. You're wasting time.	3	physicians?
4	MR. SNELL: I'm not wasting your time. I am	4	MR. SNELL: Object; leading, foundation,
5	giving a proper objection. You are the one that	5	outside the scope.
6	noticed a trial deposition.	6	BY THE WITNESS:
7	MR. THORNBURGH: Just get Judge Greenspan's	7	A. Yes, I have an opinion.
8	office, please.	8	BY MR. THORNBURGH:
9	BY MR. THORNBURGH:	9	Q. What's that opinion?
10	Q. Doctor, do you have an opinion about	10	A. That is inappropriate.
11	whether or not the marketing person should be	11	Q. Doctor, was the need for a complete
12	calling the shots on what safety information is	12	removal of a TVT device ever common knowledge?
13	provided to physicians?	13	MR. SNELL: Object. I believe that's outside
14	MR. SNELL: Object; leading, foundation,	14	the scope of his report, unless you want to show me
15	outside the scope, improper expert subject matter	15	that opinion.
16	now.	16	BY MR. THORNBURGH:
17	BY THE WITNESS:	17	Q. Do you know, Doctor?
18	A. I do have an opinion.	18	A. No, it was not common knowledge.
19	BY MR. THORNBURGH:	19	Q. Was the ability to surgically remove
20	Q. What is that?	20	these TVT devices ever commonly known?
21	A. They should not.	21	MR. SNELL: Same objection; outside the scope.
22	Q. Doctor, do you know whether or not	22	BY THE WITNESS:
23	Ethicon ever provided instructions or training on	23	A. No.
24	how to remove a any of its TVT products in the	24	BY MR. THORNBURGH:
	Page 71		Page 73
1	event of a complication?	1	Q. Were the was it a technique for the
2	A. No, they did not.	2	removal of these TVT products, including the
3	Q. And is that significant at all to your	3	TVT-Secur, ever commonly known?
4	opinions?	4	MR. SNELL: Same objection. Dr. Rosenzweig
5	A. Yes.	5	does not have common known opinions in his report.
6	Q. What is that?	6	Go ahead.
7	A. That if a device is being placed in the	7	BY THE WITNESS:
8	body permanently, there should be a known,	8	A. No.
9	reliable, tested method for not only implanting the	9	BY MR. THORNBURGH:
		10	O W
10	device but also removal of the device.	1 10	Q. Were you ever trained by Ethicon on the
10 11	device but also removal of the device.  Q. Dr. Klutke, is he a medical doctor?	11	proper technique needed to safely remove its TVT
			•
11	Q. Dr. Klutke, is he a medical doctor?	11	proper technique needed to safely remove its TVT line of products in the event of complications?  A. No.
11 12	<ul><li>Q. Dr. Klutke, is he a medical doctor?</li><li>A. Yes.</li></ul>	11 12	proper technique needed to safely remove its TVT line of products in the event of complications?
11 12 13	<ul><li>Q. Dr. Klutke, is he a medical doctor?</li><li>A. Yes.</li><li>Q. Dr. Hellhammer, is she a medical doctor?</li></ul>	11 12 13	proper technique needed to safely remove its TVT line of products in the event of complications?  A. No.
11 12 13 14	<ul><li>Q. Dr. Klutke, is he a medical doctor?</li><li>A. Yes.</li><li>Q. Dr. Hellhammer, is she a medical doctor?</li><li>MR. SNELL: Object; covered.</li></ul>	11 12 13 14	proper technique needed to safely remove its TVT line of products in the event of complications?  A. No.  Q. Prior to your involvement in this
11 12 13 14 15	<ul> <li>Q. Dr. Klutke, is he a medical doctor?</li> <li>A. Yes.</li> <li>Q. Dr. Hellhammer, is she a medical doctor?</li> <li>MR. SNELL: Object; covered.</li> <li>BY THE WITNESS:</li> <li>A. No.</li> <li>BY MR. THORNBURGH:</li> </ul>	11 12 13 14 15	proper technique needed to safely remove its TVT line of products in the event of complications?  A. No.  Q. Prior to your involvement in this litigation, were you ever shown this internal
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11 12 13 14 15 16	<ul> <li>Q. Dr. Klutke, is he a medical doctor?</li> <li>A. Yes.</li> <li>Q. Dr. Hellhammer, is she a medical doctor?</li> <li>MR. SNELL: Object; covered.</li> <li>BY THE WITNESS:</li> <li>A. No.</li> <li>BY MR. THORNBURGH:</li> </ul>	11 12 13 14 15 16 17	proper technique needed to safely remove its TVT line of products in the event of complications?  A. No. Q. Prior to your involvement in this litigation, were you ever shown this internal company document?  A. No.
11 12 13 14 15 16 17	<ul> <li>Q. Dr. Klutke, is he a medical doctor?</li> <li>A. Yes.</li> <li>Q. Dr. Hellhammer, is she a medical doctor?</li> <li>MR. SNELL: Object; covered.</li> <li>BY THE WITNESS: <ul> <li>A. No.</li> </ul> </li> <li>BY MR. THORNBURGH: <ul> <li>Q. Ms. Angelini, is she a medical doctor?</li> </ul> </li> </ul>	11 12 13 14 15 16 17 18	proper technique needed to safely remove its TVT line of products in the event of complications?  A. No.  Q. Prior to your involvement in this litigation, were you ever shown this internal company document?  A. No.  Q. Were doctors in the community, to the
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19 (Pages 70 to 73)

	Page 74		Page 76
1	BY MR. THORNBURGH:	1	wise to be more elusive on this."
2	Q. What's the next exhibit in your binder	2	Did I read that correctly?
3	that you'd like to discuss with the jury?	3	A. Yes.
4	A. It's an e-mail from Dr. Axel Arnaud, who	4	Q. How does that support your opinion,
5	is a Medical Director, to Dr. Martin Weisberg, also	5	Doctor?
6	a Medical Director, from October of 2002.	6	A. It is
7	MR. SNELL: Object; improper Pennsylvania	7	MR. SNELL: Object; asked and answered. Go
8	procedure.	8	ahead.
9	BY MR. THORNBURGH:	9	BY THE WITNESS:
10	Q. And is this P1080?	10	A improper to be elusive about
11	A. Correct.	11	complications associated with a medical device.
12	Q. And what is the significance of	12	BY MR. THORNBURGH:
13	MR. SNELL: Can I have a copy, counsel.	13	Q. Why is it improper to be elusive about
14	MR. THORNBURGH: I'm sorry.	14	complications associated with a medical device,
15	BY MR. THORNBURGH:	15	Doctor?
16	Q. How is this e-mail between Axel Arnaud	16	A. Because doctors need to be informed
17	and Marty Weisberg significant, if at all, to your	17	about that. The manufacturer is the one that has
18	opinions in this case?	18	the most information, the most resources to know
19	A. They're discussing a complication of the	19	about complications associated with their devices
20	Prolene mesh called an erosion. I've described	20	and they should be frank about discussing that with
21	that earlier for the jury what an erosion is, but	21	physicians so that physicians know about the
22	basically it's when the the vagina that is	22	complications associated with their device.
23	covering the mesh dies away and the mesh is now	23	Q. Why should physicians know about
24	exposes an ulcer into the vagina.	24	complications associated with medical devices?
	Page 75		Page 77
1	And what Dr. Arnaud is stating, that it	1	A. So that they can discuss that with their
2	might be wise to be more elusive about this topic	2	patients so that the patient can ultimately make an
3	of mesh erosion.	3	informed decision about the treatment that they
4	O Okay And for the record who is Aval		·
	Q. Okay. And for the record who is Axel	4	get, the devices that are being used. It's
5	Arnaud?	4 5	get, the devices that are being used. It's ultimately up to the patient to make the decision
	Arnaud?  A. A Medical Director and also a doctor.		get, the devices that are being used. It's ultimately up to the patient to make the decision about the treatment that she has and which devices
5 6 7	Arnaud?  A. A Medical Director and also a doctor.  Q. And who is Martin Weisberg?	5 6 7	get, the devices that are being used. It's ultimately up to the patient to make the decision about the treatment that she has and which devices will be used to accomplish that treatment.
5 6 7 8	Arnaud?  A. A Medical Director and also a doctor.  Q. And who is Martin Weisberg?  A. A Medical Director and also a doctor.	5 6 7 8	get, the devices that are being used. It's ultimately up to the patient to make the decision about the treatment that she has and which devices will be used to accomplish that treatment.  Q. Do you have an opinion about whether or
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Arnaud?  A. A Medical Director and also a doctor.  Q. And who is Martin Weisberg?  A. A Medical Director and also a doctor.  Q. Do you have an opinion whether or not it is okay strike that.  Do you have an opinion whether or not being elusive about safety information is proper?  A. I do have an opinion.  Q. What's that opinion?  A. It is not proper.  Q. And go ahead and highlight for us the first paragraph here.  It says, "Dear Doctor, I reviewed your draft report. Apart from minor corrections concerning typing errors, it is perfect for me. I just had a concern about your statement concerning	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	get, the devices that are being used. It's ultimately up to the patient to make the decision about the treatment that she has and which devices will be used to accomplish that treatment.  Q. Do you have an opinion about whether or not do you have an opinion about what could happen to patients if medical device companies are elusive about safety information?  MR. SNELL: Objection; outside the scope of his report. Not an opinion he's expressed.  BY THE WITNESS:  A. That patient safety is compromised.  BY MR. THORNBURGH:  Q. What does that mean, "patient safety is compromised"?  MR. SNELL: Same objection.  BY THE WITNESS:  A. That patients unfortunately would be
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Arnaud?  A. A Medical Director and also a doctor.  Q. And who is Martin Weisberg?  A. A Medical Director and also a doctor.  Q. Do you have an opinion whether or not it is okay strike that.  Do you have an opinion whether or not being elusive about safety information is proper?  A. I do have an opinion.  Q. What's that opinion?  A. It is not proper.  Q. And go ahead and highlight for us the first paragraph here.  It says, "Dear Doctor, I reviewed your draft report. Apart from minor corrections concerning typing errors, it is perfect for me. I just had a concern about your statement concerning potential complications/fistula and erosions. This	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	get, the devices that are being used. It's ultimately up to the patient to make the decision about the treatment that she has and which devices will be used to accomplish that treatment.  Q. Do you have an opinion about whether or not do you have an opinion about what could happen to patients if medical device companies are elusive about safety information?  MR. SNELL: Objection; outside the scope of his report. Not an opinion he's expressed.  BY THE WITNESS:  A. That patient safety is compromised.  BY MR. THORNBURGH:  Q. What does that mean, "patient safety is compromised"?  MR. SNELL: Same objection.  BY THE WITNESS:  A. That patients unfortunately would be exposed to complications that they might not be
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Arnaud?  A. A Medical Director and also a doctor.  Q. And who is Martin Weisberg?  A. A Medical Director and also a doctor.  Q. Do you have an opinion whether or not it is okay strike that.  Do you have an opinion whether or not being elusive about safety information is proper?  A. I do have an opinion.  Q. What's that opinion?  A. It is not proper.  Q. And go ahead and highlight for us the first paragraph here.  It says, "Dear Doctor, I reviewed your draft report. Apart from minor corrections concerning typing errors, it is perfect for me. I just had a concern about your statement concerning potential complications/fistula and erosions. This is a problem which arises rather commonly in	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	get, the devices that are being used. It's ultimately up to the patient to make the decision about the treatment that she has and which devices will be used to accomplish that treatment.  Q. Do you have an opinion about whether or not do you have an opinion about what could happen to patients if medical device companies are elusive about safety information?  MR. SNELL: Objection; outside the scope of his report. Not an opinion he's expressed.  BY THE WITNESS:  A. That patient safety is compromised.  BY MR. THORNBURGH:  Q. What does that mean, "patient safety is compromised"?  MR. SNELL: Same objection.  BY THE WITNESS:  A. That patients unfortunately would be exposed to complications that they might not be exposed to. Quite frankly, the patients would end
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Arnaud?  A. A Medical Director and also a doctor.  Q. And who is Martin Weisberg?  A. A Medical Director and also a doctor.  Q. Do you have an opinion whether or not it is okay strike that.  Do you have an opinion whether or not being elusive about safety information is proper?  A. I do have an opinion.  Q. What's that opinion?  A. It is not proper.  Q. And go ahead and highlight for us the first paragraph here.  It says, "Dear Doctor, I reviewed your draft report. Apart from minor corrections concerning typing errors, it is perfect for me. I just had a concern about your statement concerning potential complications/fistula and erosions. This	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	get, the devices that are being used. It's ultimately up to the patient to make the decision about the treatment that she has and which devices will be used to accomplish that treatment.  Q. Do you have an opinion about whether or not do you have an opinion about what could happen to patients if medical device companies are elusive about safety information?  MR. SNELL: Objection; outside the scope of his report. Not an opinion he's expressed.  BY THE WITNESS:  A. That patient safety is compromised.  BY MR. THORNBURGH:  Q. What does that mean, "patient safety is compromised"?  MR. SNELL: Same objection.  BY THE WITNESS:  A. That patients unfortunately would be exposed to complications that they might not be

	Page 78		Page 80
1	BY MR. THORNBURGH:	1	intercourse, obstruction of voiding and mesh
2	Q. What's the next document you'd like to	2	erosion.
3	discuss with the jury today?	3	Q. Now, we'll get to the Information for
4	MR. SNELL: Object; improper Pennsylvania	4	Use in a little bit in greater detail. But did
5	procedure. Can I have a copy?	5	Ethicon ever indicate in the Information for Use
6	BY THE WITNESS:	6	for the TVT-Secur device that the TVT-Secur device,
7	A. This is an e-mail from Medical Director	7	once implanted, could shrink up to 30%?
8	Axel Arnaud to several key Ethicon employees,	8	A. No, they did not.
9	including engineer Gene Kammerer.	9	Q. Doctor, based on your review of the
10	MR. SNELL: Give me a second, Doctor. Before	10	internal documents, did Ethicon strike that.
11	we go reading. Okay.	11	Did Ethicon do you have an opinion
12	MR. THORNBURGH: I don't know if I did this.	12	strike that.
13	But let's go ahead and mark the entire binder as	13	Do you have an opinion whether or not
14	Exhibit BR-Secur 5.	14	Ethicon ever disclosed to the world or to
15	(WHEREUPON, a binder was marked as	15	physicians that their TVT line of products could
16	BR-Secur Exhibit No. 5: Binder of	16	shrink up to 30%?
17	various Plaintiffs' Exhibits	17	A. No.
18	referred to by deponent.)	18	MR. SNELL: Objection; outside the scope of
19	BY MR. THORNBURGH:	19	the report.
20	Q. Okay. So, you were discussing	20	BY THE WITNESS:
21	Exhibit P933, which is within Exhibit 5, the	21	A. No.
22	binder.	22	BY MR. THORNBURGH:
23	How is Exhibit P0933 strike that.	23	Q. What's the basis for that opinion,
24	Is did you rely on Exhibit strike	24	Doctor?
	Page 79		Page 81
1	that.	1	A. The review of internal documents and
2	Did you rely on Exhibit P0933?	2	deposition testimony.
3	A. Yes.	3	Q. Doctor, when was the first time you
4	Q. And how does Exhibit P0933 support your	4	learned that the TVT products, including the TVT-R,
5	opinions in this case?	5	Retropubic, the TVT-O, Obturator, or the TVT-S, the
6	A. This document describes e-mail between	6	Secur, could shrink up to 30% after implant in the
7	key Ethicon employees and it documents that	7	human body?
8	Dr. Axel Arnaud knew that mesh contracted or shrank	8	Did you know this before you became
9	30%.	9	involved as an expert in this litigation?
10	MR. SNELL: Object; improper state of mind	10	A. I understood that from the literature
11	opinion.	11	that there could be mesh contraction.
12	BY MR. THORNBURGH:	12	Q. Did you understand that Ethicon was
13	Q. And how is shrinkage, a 30% shrinkage	13	aware that up to 30% of its meshes 30% of the
14	strike that.	14	TVT device devices could retract or shrink?
15	How is the fact that Axel Arnaud writes	15	MR. SNELL: Objection; misstates the evidence,
16	or agrees that shrinkage can occur up to 30% of an	16	state of mind as to Ethicon.
1 -	implanted TVT mesh relevant to your opinions?	17	BY THE WITNESS:
17		18	A. I had not seen this e-mail prior to
17 18	A live already described the importance of	1 -0	becoming involved in this litigation.
18	A. I've already described the importance of	10	
18 19	mesh contraction, deformation caused by the chronic	19 20	_
18 19 20	mesh contraction, deformation caused by the chronic foreign body reaction, chronic inflammatory	20	BY MR. THORNBURGH:
18 19 20 21	mesh contraction, deformation caused by the chronic foreign body reaction, chronic inflammatory reaction.	20 21	BY MR. THORNBURGH: Q. Did Ethicon share this e-mail with
18 19 20 21 22	mesh contraction, deformation caused by the chronic foreign body reaction, chronic inflammatory reaction.  A 30% shrinkage is a significant degree	20 21 22	BY MR. THORNBURGH:  Q. Did Ethicon share this e-mail with anybody outside of Ethicon?
18 19 20 21	mesh contraction, deformation caused by the chronic foreign body reaction, chronic inflammatory reaction.	20 21	BY MR. THORNBURGH: Q. Did Ethicon share this e-mail with

	Page 82		Page 84
1	A. No.	1	Q. What is the next document that you'd
2	MR. SNELL: Outside the scope.	2	like to discuss with the ladies and gentlemen of
3	BY MR. THORNBURGH:	3	the jury and how does it support your opinions?
4	Q. Was it common knowledge in the medical	4	MR. SNELL: Object; improper Pennsylvania
5	community that the TVT devices, including the	5	procedure. Go ahead.
6	TVT-Secur, could shrink up to 30%?	6	BY THE WITNESS:
7	MR. SNELL: Object; outside the scope.	7	A. This is an e-mail which is from
8	BY THE WITNESS:	8	December of 2004.
9	A. No.	9	BY MR. THORNBURGH:
10	BY MR. THORNBURGH:	10	Q. And for the record just identify the
11	Q. Was it disclosed outside of Ethicon by	11	exhibit number.
12	Ethicon to physicians that their TVT devices,	12	MR. SNELL: Can I get a copy too.
13	including the TVT-Secur, could shrink up to 30%?	13	MR. THORNBURGH: I'm sorry.
14	MR. SNELL: Objection; outside the report.	14	BY THE WITNESS:
15	BY THE WITNESS:	15	A. It is P1572.
16	A. No.	16	BY MR. THORNBURGH:
17	BY MR. THORNBURGH:	17	O. Okay. And what is this document?
18	Q. How is this document significant to your	18	A. It is an e-mail. Attached to it is
19	opinions?	19	what's called the charter document which for
20	A. That this describes the scientific	20	what was described as the TVT X. TVT X is the code
21	knowledge of the Medical Director and the	21	name, if you will, during the development phase of
22	discussion among key Ethicon employees regarding	22	the TVT-Secur before it became the TVT-Secur.
23	the rate of shrinkage or the degree of shrinkage of	23	And it is the charter document is a
24	a TVT device.	24	document to describe to management why they should
21	a 1 v 1 device.		document to describe to management why they should
	Page 83		Page 85
1	MR. SNELL: Improper state of mind. Object.	1	go forward with the TVT X project.
2	BY MR. THORNBURGH:	2	Q. Okay. And how does this document
3	Q. What can happen to patients if the mesh	3	strike that.
4	shrinks up to 30%?	4	What is significant about Exhibit P1527?
5	A. As I've described in prior testimony,	5	A. Well, this is from the project leader
6	mesh contraction up to this degree can lead to	6	Dan Smith. Dan Smith is an engineer at Ethicon.
7	complications such as pain, pain with intercourse,	7	And this describes the annual sales for the current
8	mesh erosion, and obstructed voiding.	8	products, the TVT and the TVT-O. It's estimated to
9	MR. THORNBURGH: Take a quick break.	9	reach 100 million by the end of 2004 with a 91%
10	THE VIDEOGRAPHER: Okay. The time is 10:39	10	profitability, that the new product that is being
11	a.m. This is the end of Tape 1 and we are going	11	described in this charter document, the TVT X,
12	off the video record.	12	which ultimately became the TVT-Secur, will help
13	(WHEREUPON, a recess was had	13	Gynecare and Ethicon maintain their market
14	from 10:39 to 10:48 a.m.)	14	dominance. However, it is important for them to
15	THE VIDEOGRAPHER: The time is 10:48 a.m.	15	stay ahead of
16	This is the beginning of Tape 2 and we're back on	16	Q. Go ahead.
17	the video record.	17	A the competition and that being the
18	BY MR. THORNBURGH:	18	first to market with a new device such as the TVT X
19	Q. Doctor, before we went off the record we	19	would be, quote-unquote, "priceless."
20	were talking about your opinions, summary of	20	Q. Now
21	opinions that you provided earlier and the bases	21	MR. SNELL: Object. Object. Move to strike
	for those opinions including the internal documents	22	the entire answer as non-responsive and improper
22	1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	1	
22 23	that you have shown us so far?	23	subject matter.
	that you have shown us so far?  A. Yes.	23 24	subject matter. BY MR. THORNBURGH:

22 (Pages 82 to 85)

	Page 86		Page 88
1	Q. Now, Doctor, is it improper for a	1	Q. What, if anything, should a company do
2	medical device company to want to be first to	2	if it determines prior to launch that its product
3	market?	3	is not efficacious or is unsafe?
4	MR. SNELL: Object; state of mind, outside the	4	A. They should not launch the product.
5	scope of the report.	5	Q. Is it ever okay for a company such as
6	BY THE WITNESS:	6	Ethicon and Johnson & Johnson to be motivated by
7	A. It is not improper to want to be the	7	profits over providing safe and effective care and
8	first to market.	8	treatment to patients?
9	BY MR. THORNBURGH:	9	MR. SNELL: Object; improper expert opinion,
10	Q. And and when does it become improper?	10	state of mind.
11	MR. SNELL: Same objection.	11	BY THE WITNESS:
12	BY MR. THORNBURGH:	12	A. No, it is not.
13	O. Does it ever strike that.	13	BY MR. THORNBURGH:
14	Does it ever become improper?	14	Q. Why is that?
15	MR. SNELL: Same objections, requires	15	A. Because then patient safety is
16	sorry. Lacks foundation.	16	compromised and patients would be exposed to an
17	BY THE WITNESS:	17	undue amount of complications.
18	A. Yes, it does.	18	Q. Okay. And, so, if we look at the
19	BY MR. THORNBURGH:	19	Exhibit P1527 and go to ETH.MESH.07898854, which is
20	O. And when is that?	20	the first page of the attachment of the e-mail.
21	A. When a product is not adequately tested	21	And I think this describes some of what
22	prior to it being launched to be able to understand	22	you've just testified about. This is the charter
23	the safety and efficacy of the product prior to	23	document, is that correct?
24	being launched.	24	A. Correct.
	Page 87		Page 89
1	Q. Fair enough. So, it's I think if I	1	Q. And who is Dan Smith?
2	understand you correctly, it's okay to be first to	2	A. Dan Smith is an engineer and the project
3	market with your product as long as you do it in an	3	leader for the TVT X project, which ultimately
4	appropriate way?	4	became the TVT-Secur.
5	MR. SNELL: Objection; leading.	5	Q. Was Dan Smith a medical doctor?
6	BY MR. THORNBURGH:	6	A. No.
7	Q. Is that correct?	7	Q. Was Dan Smith a gynecologist?
8	A. Correct.	8	A. No.
9	MR. SNELL: Leading, repetition.	9	Q. Was Dan Smith a urogynecologist?
10	BY MR. THORNBURGH:	10	A. No.
11	Q. And to do it, what needs to be done in	11	Q. Who invented the TVT-Secur?
12	order to become to bring your product and be the	12	A. Dan Smith was one of the was the lead
13	first to market in a way that also provides safety	13	engineer on the TVT-Secur project.
14	for patients?	14	Q. And this document says that the "annual
15	MR. SNELL: Overbroad.	15	sales of the Gynecare TVT brand (TVT and TVT-O) in
16	BY MR. THORNBURGH:	16	the direct markets is estimated to reach somewhere
17	Q. That also considers safety for patients?	17	around \$100 million by the end of 2004 with a
18	MR. SNELL: Object; overbroad.	18	profitability of around 91%."
19	BY THE WITNESS:	19	Did I read that correctly?
20	A. Product has to be designed, evaluated	20	MR. SNELL: Objection.
21	and tested in order to make sure that the	21	BY THE WITNESS:
22	characteristics of the device are safe and that the	22	A. Yes.
ı		1	
23	device performs as it's intended.	23	MR. SNELL: Leading and improper expert
23 24	device performs as it's intended. BY MR. THORNBURGH:	23	MR. SNELL: Leading and improper expert subject matter. The jury can read an e-mail for

23 (Pages 86 to 89)

	Page 90		Page 92
1	themselves.	1	it and it's asked and answered, repetition.
2	BY MR. THORNBURGH:	2	MR. THORNBURGH: Could you try not to speak
3	Q. If you go down to the last sentence in	3	over me or object over the question or the answer.
4	the first in this first section it says, "It	4	MR. SNELL: I'm not trying to object over the
5	remains strongly recognized that Gynecare developed	5	answer.
6	this market and coupled with the skills,	6	MR. THORNBURGH: We have to cut this later on.
7	competencies and capabilities within the	7	MR. SNELL: I know. I'm trying to wait for
8	organization, such market dominance can be	8	you to finish. But please give me a break, sir.
9	sustained. However, product innovation and	9	THE WITNESS: Yes, sir.
10	advancement is required in order to stay ahead of	10	MR. SNELL: I know. I don't mean to step on
11	the competition."	11	you at all. I just need to I have to get my
12	Did I read that correctly?	12	objection in.
13	A. Yes.	13	I'll try to wait until you finish, Dan.
14	MR. SNELL: Object; leading, improper expert	14	BY MR. THORNBURGH:
15	subject matter. The jury can read documents	15	Q. Is the TVT-Secur a permanent implantable
16	themselves.	16	device?
17	BY MR. THORNBURGH:	17	MR. SNELL: Object; repetition, asked and
18	Q. And is it improper to try to stay ahead	18	answered.
19	of competition?	19	BY THE WITNESS:
20	A. No.	20	A. Yes.
21	Q. Does it ever become improper?	21	BY MR. THORNBURGH:
22	A. If	22	Q. In light of that fact, would it be
23	MR. SNELL: Object; vague, overbroad.	23	proper for Ethicon to rush a product to the
24	BY THE WITNESS:	24	market
	Page 91		Page 93
1	A. If a device is not properly tested to	1	MR. SNELL: Object.
2			
	assure that it is safe and effective.	2	BY MR. THORNBURGH:
3	BY MR. THORNBURGH:	3	BY MR. THORNBURGH: Q without properly testing it?
4	BY MR. THORNBURGH:  Q. And what can happen to patients if	3 4	BY MR. THORNBURGH: Q without properly testing it? A. No.
4 5	BY MR. THORNBURGH:  Q. And what can happen to patients if devices aren't properly tested?	3 4 5	BY MR. THORNBURGH:  Q without properly testing it?  A. No.  Q. This is serious business, isn't it?
4 5 6	BY MR. THORNBURGH:  Q. And what can happen to patients if devices aren't properly tested?  A. Patients are exposed	3 4 5 6	BY MR. THORNBURGH: Q without properly testing it? A. No. Q. This is serious business, isn't it? MR. SNELL: Object; leading, argumentative.
4 5 6 7	BY MR. THORNBURGH:  Q. And what can happen to patients if devices aren't properly tested?  A. Patients are exposed MR. SNELL: Objection; requires speculation	3 4 5 6 7	BY MR. THORNBURGH: Q without properly testing it? A. No. Q. This is serious business, isn't it? MR. SNELL: Object; leading, argumentative. BY MR. THORNBURGH:
4 5 6 7 8	BY MR. THORNBURGH:  Q. And what can happen to patients if devices aren't properly tested?  A. Patients are exposed MR. SNELL: Objection; requires speculation without foundation.	3 4 5 6 7 8	BY MR. THORNBURGH: Q without properly testing it? A. No. Q. This is serious business, isn't it? MR. SNELL: Object; leading, argumentative. BY MR. THORNBURGH: Q. Is this serious business?
4 5 6 7 8 9	BY MR. THORNBURGH:  Q. And what can happen to patients if devices aren't properly tested?  A. Patients are exposed MR. SNELL: Objection; requires speculation without foundation. BY THE WITNESS:	3 4 5 6 7 8	BY MR. THORNBURGH: Q without properly testing it? A. No. Q. This is serious business, isn't it? MR. SNELL: Object; leading, argumentative. BY MR. THORNBURGH: Q. Is this serious business? A. Yes.
4 5 6 7 8 9	BY MR. THORNBURGH:  Q. And what can happen to patients if devices aren't properly tested?  A. Patients are exposed MR. SNELL: Objection; requires speculation without foundation.  BY THE WITNESS:  A. Patients are exposed to risks of safety	3 4 5 6 7 8 9	BY MR. THORNBURGH: Q without properly testing it? A. No. Q. This is serious business, isn't it? MR. SNELL: Object; leading, argumentative. BY MR. THORNBURGH: Q. Is this serious business? A. Yes. Q. This is a serious issue that we are
4 5 6 7 8 9 10	BY MR. THORNBURGH: Q. And what can happen to patients if devices aren't properly tested? A. Patients are exposed MR. SNELL: Objection; requires speculation without foundation. BY THE WITNESS: A. Patients are exposed to risks of safety or in or lack of efficacy of the product that	3 4 5 6 7 8 9 10	BY MR. THORNBURGH: Q without properly testing it? A. No. Q. This is serious business, isn't it? MR. SNELL: Object; leading, argumentative. BY MR. THORNBURGH: Q. Is this serious business? A. Yes. Q. This is a serious issue that we are talking about here?
4 5 6 7 8 9 10 11	BY MR. THORNBURGH:  Q. And what can happen to patients if devices aren't properly tested?  A. Patients are exposed MR. SNELL: Objection; requires speculation without foundation.  BY THE WITNESS:  A. Patients are exposed to risks of safety or in or lack of efficacy of the product that they are being used that is permanently implanted	3 4 5 6 7 8 9 10 11 12	BY MR. THORNBURGH: Q without properly testing it? A. No. Q. This is serious business, isn't it? MR. SNELL: Object; leading, argumentative. BY MR. THORNBURGH: Q. Is this serious business? A. Yes. Q. This is a serious issue that we are talking about here? A. Yes.
4 5 6 7 8 9 10	BY MR. THORNBURGH:  Q. And what can happen to patients if devices aren't properly tested?  A. Patients are exposed MR. SNELL: Objection; requires speculation without foundation.  BY THE WITNESS:  A. Patients are exposed to risks of safety or in or lack of efficacy of the product that they are being used that is permanently implanted product that is supposed to be in them for the rest	3 4 5 6 7 8 9 10	BY MR. THORNBURGH: Q without properly testing it? A. No. Q. This is serious business, isn't it? MR. SNELL: Object; leading, argumentative. BY MR. THORNBURGH: Q. Is this serious business? A. Yes. Q. This is a serious issue that we are talking about here? A. Yes. Q. Is the health and well-being of women
4 5 6 7 8 9 10 11 12 13 14	BY MR. THORNBURGH:  Q. And what can happen to patients if devices aren't properly tested?  A. Patients are exposed MR. SNELL: Objection; requires speculation without foundation.  BY THE WITNESS:  A. Patients are exposed to risks of safety or in or lack of efficacy of the product that they are being used that is permanently implanted product that is supposed to be in them for the rest of their lives.	3 4 5 6 7 8 9 10 11 12 13 14	BY MR. THORNBURGH: Q without properly testing it? A. No. Q. This is serious business, isn't it? MR. SNELL: Object; leading, argumentative. BY MR. THORNBURGH: Q. Is this serious business? A. Yes. Q. This is a serious issue that we are talking about here? A. Yes. Q. Is the health and well-being of women important?
4 5 6 7 8 9 10 11 12 13 14	BY MR. THORNBURGH:  Q. And what can happen to patients if devices aren't properly tested?  A. Patients are exposed MR. SNELL: Objection; requires speculation without foundation.  BY THE WITNESS:  A. Patients are exposed to risks of safety or in or lack of efficacy of the product that they are being used that is permanently implanted product that is supposed to be in them for the rest of their lives.  Q. This is a permanent TVT-Secur is a	3 4 5 6 7 8 9 10 11 12 13 14 15	BY MR. THORNBURGH:  Q without properly testing it?  A. No.  Q. This is serious business, isn't it?  MR. SNELL: Object; leading, argumentative.  BY MR. THORNBURGH:  Q. Is this serious business?  A. Yes.  Q. This is a serious issue that we are talking about here?  A. Yes.  Q. Is the health and well-being of women important?  A. Yes.
4 5 6 7 8 9 10 11 12 13 14 15 16	BY MR. THORNBURGH:  Q. And what can happen to patients if devices aren't properly tested?  A. Patients are exposed MR. SNELL: Objection; requires speculation without foundation.  BY THE WITNESS:  A. Patients are exposed to risks of safety or in or lack of efficacy of the product that they are being used that is permanently implanted product that is supposed to be in them for the rest of their lives.  Q. This is a permanent TVT-Secur is a permanent implantable device, right?	3 4 5 6 7 8 9 10 11 12 13 14 15 16	BY MR. THORNBURGH:  Q without properly testing it?  A. No.  Q. This is serious business, isn't it?  MR. SNELL: Object; leading, argumentative.  BY MR. THORNBURGH:  Q. Is this serious business?  A. Yes.  Q. This is a serious issue that we are talking about here?  A. Yes.  Q. Is the health and well-being of women important?  A. Yes.  Q. Should companies consider the health and
4 5 6 7 8 9 10 11 12 13 14 15 16 17	BY MR. THORNBURGH:  Q. And what can happen to patients if devices aren't properly tested?  A. Patients are exposed MR. SNELL: Objection; requires speculation without foundation.  BY THE WITNESS:  A. Patients are exposed to risks of safety or in or lack of efficacy of the product that they are being used that is permanently implanted product that is supposed to be in them for the rest of their lives.  Q. This is a permanent TVT-Secur is a permanent implantable device, right?  A. Right.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	BY MR. THORNBURGH: Q without properly testing it? A. No. Q. This is serious business, isn't it? MR. SNELL: Object; leading, argumentative. BY MR. THORNBURGH: Q. Is this serious business? A. Yes. Q. This is a serious issue that we are talking about here? A. Yes. Q. Is the health and well-being of women important? A. Yes. Q. Should companies consider the health and well-being to be important?
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	BY MR. THORNBURGH:  Q. And what can happen to patients if devices aren't properly tested?  A. Patients are exposed MR. SNELL: Objection; requires speculation without foundation.  BY THE WITNESS:  A. Patients are exposed to risks of safety or in or lack of efficacy of the product that they are being used that is permanently implanted product that is supposed to be in them for the rest of their lives.  Q. This is a permanent TVT-Secur is a permanent implantable device, right?  A. Right.  MR. SNELL: Object. Hold on. Leading.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	BY MR. THORNBURGH:  Q without properly testing it?  A. No.  Q. This is serious business, isn't it?  MR. SNELL: Object; leading, argumentative.  BY MR. THORNBURGH:  Q. Is this serious business?  A. Yes.  Q. This is a serious issue that we are talking about here?  A. Yes.  Q. Is the health and well-being of women important?  A. Yes.  Q. Should companies consider the health and well-being to be important?  MR. SNELL: Object; repetition.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	BY MR. THORNBURGH:  Q. And what can happen to patients if devices aren't properly tested?  A. Patients are exposed MR. SNELL: Objection; requires speculation without foundation.  BY THE WITNESS:  A. Patients are exposed to risks of safety or in or lack of efficacy of the product that they are being used that is permanently implanted product that is supposed to be in them for the rest of their lives.  Q. This is a permanent TVT-Secur is a permanent implantable device, right?  A. Right.  MR. SNELL: Object. Hold on. Leading.  MR. THORNBURGH: He already testified	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	BY MR. THORNBURGH:  Q without properly testing it?  A. No.  Q. This is serious business, isn't it?  MR. SNELL: Object; leading, argumentative.  BY MR. THORNBURGH:  Q. Is this serious business?  A. Yes.  Q. This is a serious issue that we are talking about here?  A. Yes.  Q. Is the health and well-being of women important?  A. Yes.  Q. Should companies consider the health and well-being to be important?  MR. SNELL: Object; repetition.  BY MR. THORNBURGH:
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	BY MR. THORNBURGH:  Q. And what can happen to patients if devices aren't properly tested?  A. Patients are exposed MR. SNELL: Objection; requires speculation without foundation.  BY THE WITNESS:  A. Patients are exposed to risks of safety or in or lack of efficacy of the product that they are being used that is permanently implanted product that is supposed to be in them for the rest of their lives.  Q. This is a permanent TVT-Secur is a permanent implantable device, right?  A. Right.  MR. SNELL: Object. Hold on. Leading.  MR. THORNBURGH: He already testified MR. SNELL: Leading, asked and answered three	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	BY MR. THORNBURGH: Q without properly testing it? A. No. Q. This is serious business, isn't it? MR. SNELL: Object; leading, argumentative. BY MR. THORNBURGH: Q. Is this serious business? A. Yes. Q. This is a serious issue that we are talking about here? A. Yes. Q. Is the health and well-being of women important? A. Yes. Q. Should companies consider the health and well-being to be important? MR. SNELL: Object; repetition. BY MR. THORNBURGH: Q. Strike that.
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY MR. THORNBURGH:  Q. And what can happen to patients if devices aren't properly tested?  A. Patients are exposed MR. SNELL: Objection; requires speculation without foundation.  BY THE WITNESS:  A. Patients are exposed to risks of safety or in or lack of efficacy of the product that they are being used that is permanently implanted product that is supposed to be in them for the rest of their lives.  Q. This is a permanent TVT-Secur is a permanent implantable device, right?  A. Right.  MR. SNELL: Object. Hold on. Leading.  MR. THORNBURGH: He already testified MR. SNELL: Leading, asked and answered three times. Go ahead.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY MR. THORNBURGH:  Q without properly testing it?  A. No.  Q. This is serious business, isn't it?  MR. SNELL: Object; leading, argumentative.  BY MR. THORNBURGH:  Q. Is this serious business?  A. Yes.  Q. This is a serious issue that we are talking about here?  A. Yes.  Q. Is the health and well-being of women important?  A. Yes.  Q. Should companies consider the health and well-being to be important?  MR. SNELL: Object; repetition.  BY MR. THORNBURGH:  Q. Strike that.  Should companies like Ethicon and
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MR. THORNBURGH:  Q. And what can happen to patients if devices aren't properly tested?  A. Patients are exposed MR. SNELL: Objection; requires speculation without foundation.  BY THE WITNESS:  A. Patients are exposed to risks of safety or in or lack of efficacy of the product that they are being used that is permanently implanted product that is supposed to be in them for the rest of their lives.  Q. This is a permanent TVT-Secur is a permanent implantable device, right?  A. Right.  MR. SNELL: Object. Hold on. Leading. MR. THORNBURGH: He already testified MR. SNELL: Leading, asked and answered three times. Go ahead.  MR. THORNBURGH: It's not leading if he's	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MR. THORNBURGH:  Q without properly testing it?  A. No. Q. This is serious business, isn't it? MR. SNELL: Object; leading, argumentative. BY MR. THORNBURGH: Q. Is this serious business? A. Yes. Q. This is a serious issue that we are talking about here? A. Yes. Q. Is the health and well-being of women important? A. Yes. Q. Should companies consider the health and well-being to be important? MR. SNELL: Object; repetition. BY MR. THORNBURGH: Q. Strike that. Should companies like Ethicon and Johnson & Johnson who develop medical devices for
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY MR. THORNBURGH:  Q. And what can happen to patients if devices aren't properly tested?  A. Patients are exposed MR. SNELL: Objection; requires speculation without foundation.  BY THE WITNESS:  A. Patients are exposed to risks of safety or in or lack of efficacy of the product that they are being used that is permanently implanted product that is supposed to be in them for the rest of their lives.  Q. This is a permanent TVT-Secur is a permanent implantable device, right?  A. Right.  MR. SNELL: Object. Hold on. Leading.  MR. THORNBURGH: He already testified MR. SNELL: Leading, asked and answered three times. Go ahead.	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY MR. THORNBURGH:  Q without properly testing it?  A. No.  Q. This is serious business, isn't it?  MR. SNELL: Object; leading, argumentative.  BY MR. THORNBURGH:  Q. Is this serious business?  A. Yes.  Q. This is a serious issue that we are talking about here?  A. Yes.  Q. Is the health and well-being of women important?  A. Yes.  Q. Should companies consider the health and well-being to be important?  MR. SNELL: Object; repetition.  BY MR. THORNBURGH:  Q. Strike that.  Should companies like Ethicon and

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	Page 94		Page 96
1	A. Yes.	1	Q. Now, in this charter document, if you
2	MR. SNELL: Object; repetition.	2	turn to if you go to the last bullet point on
3	BY MR. THORNBURGH:	3	ETH.MESH ending in 854, it says, "Being first to
4	Q. What happens if a company like Ethicon	4	market with a superior less-invasive TVT product
5	and Johnson & Johnson doesn't consider the health	5	and protecting our market share could be
6	and well-being of women to be important?	6	priceless."
7	MR. SNELL: Object; state of mind, repetition.	7	Did I read that correctly?
8	BY THE WITNESS:	8	A. Yes.
9	A. Women suffer.	9	Q. And is that what you testified to
10	BY MR. THORNBURGH:	10	earlier?
11	Q. Should the health and well-being of	11	A. Yes.
12	women be more important than beating your	12	Q. And if we turn to ETH.MESH.07898856 of
13	competition to market	13	Exhibit P1527, is there anything significant about
14	MR. SNELL: Object.	14	this next page?
15	BY MR. THORNBURGH:	15	A. This is a page has a graphic that
16	Q with a product?	16	describes what Gynecare or Gynecare is a
17	MR. SNELL: Object; repetition.	17	division of Ethicon what their market share
18	BY THE WITNESS:	18	would be without having the TVT X as part of their
19	A. Yes.	19	sales armamentarium.
20	BY MR. THORNBURGH:	20	Q. And if you look at the second bullet
21	Q. Should the health and well-being of	21	point, there is a graph underneath that second
22	women be more important to a company like Ethicon	22	bullet point. Is that the graph that you're
23	and Johnson & Johnson than how much money you're	23	referring to?
24	going to make on a given product in a given year?	24	A. Yes.
	Page 95		Page 97
1	MR. SNELL: Object; improper expert opinion.	1	Q. And what does it show would happen to
2	Outside the scope of this medical doctor's report.	2	the Gynecare market share without the TVT-Secur?
3	BY THE WITNESS:	3	MR. SNELL: Object; improper expert testimony.
4	A. Yes.	4	BY THE WITNESS:
5		_	DI THE WITNESS:
	BY MR. THORNBURGH:	5	A. There would be
6	BY MR. THORNBURGH: Q. Why is that, Doctor?		
6 7		5	A. There would be MR. SNELL: The jury can discern this for themselves.
7	<ul><li>Q. Why is that, Doctor?</li><li>A. Because the safety of the patient is paramount.</li></ul>	5 6 7 8	A. There would be MR. SNELL: The jury can discern this for themselves. BY THE WITNESS:
7	<ul><li>Q. Why is that, Doctor?</li><li>A. Because the safety of the patient is</li></ul>	5 6 7	A. There would be MR. SNELL: The jury can discern this for themselves.
7	<ul> <li>Q. Why is that, Doctor?</li> <li>A. Because the safety of the patient is paramount.</li> <li>Q. Do you have an opinion based on your review do you have an opinion whether or not</li> </ul>	5 6 7 8	A. There would be MR. SNELL: The jury can discern this for themselves. BY THE WITNESS:
7 8 9 10 11	<ul> <li>Q. Why is that, Doctor?</li> <li>A. Because the safety of the patient is paramount.</li> <li>Q. Do you have an opinion based on your review do you have an opinion whether or not Ethicon put patient safety before profits?</li> </ul>	5 6 7 8 9 10 11	A. There would be MR. SNELL: The jury can discern this for themselves. BY THE WITNESS: A. There would be a steady decline in their market share from approximately the high 60s to the low teens.
7 8 9 10 11 12	<ul> <li>Q. Why is that, Doctor?</li> <li>A. Because the safety of the patient is paramount.</li> <li>Q. Do you have an opinion based on your review do you have an opinion whether or not Ethicon put patient safety before profits?</li> <li>MR. SNELL: Objection; state of mind, improper</li> </ul>	5 6 7 8 9	A. There would be MR. SNELL: The jury can discern this for themselves. BY THE WITNESS: A. There would be a steady decline in their market share from approximately the high 60s to the
7 8 9 10 11	<ul> <li>Q. Why is that, Doctor?</li> <li>A. Because the safety of the patient is paramount.</li> <li>Q. Do you have an opinion based on your review do you have an opinion whether or not Ethicon put patient safety before profits?</li> <li>MR. SNELL: Objection; state of mind, improper expert testimony, outside the scope.</li> </ul>	5 6 7 8 9 10 11	A. There would be MR. SNELL: The jury can discern this for themselves. BY THE WITNESS: A. There would be a steady decline in their market share from approximately the high 60s to the low teens. BY MR. THORNBURGH: Q. And just above this graph it says, the
7 8 9 10 11 12	<ul> <li>Q. Why is that, Doctor?</li> <li>A. Because the safety of the patient is paramount.</li> <li>Q. Do you have an opinion based on your review do you have an opinion whether or not Ethicon put patient safety before profits?</li> <li>MR. SNELL: Objection; state of mind, improper</li> </ul>	5 6 7 8 9 10 11	A. There would be MR. SNELL: The jury can discern this for themselves. BY THE WITNESS: A. There would be a steady decline in their market share from approximately the high 60s to the low teens. BY MR. THORNBURGH: Q. And just above this graph it says, the last sentence, "It is anticipated that there will
7 8 9 10 11 12 13	<ul> <li>Q. Why is that, Doctor?</li> <li>A. Because the safety of the patient is paramount.</li> <li>Q. Do you have an opinion based on your review do you have an opinion whether or not Ethicon put patient safety before profits?</li> <li>MR. SNELL: Objection; state of mind, improper expert testimony, outside the scope.</li> <li>BY THE WITNESS: <ul> <li>A. For the TVT-Secur, yes.</li> </ul> </li> </ul>	5 6 7 8 9 10 11 12 13	A. There would be MR. SNELL: The jury can discern this for themselves. BY THE WITNESS: A. There would be a steady decline in their market share from approximately the high 60s to the low teens. BY MR. THORNBURGH: Q. And just above this graph it says, the last sentence, "It is anticipated that there will be at least two competitor mini-type devices
7 8 9 10 11 12 13	<ul> <li>Q. Why is that, Doctor?</li> <li>A. Because the safety of the patient is paramount.</li> <li>Q. Do you have an opinion based on your review do you have an opinion whether or not Ethicon put patient safety before profits?</li> <li>MR. SNELL: Objection; state of mind, improper expert testimony, outside the scope.</li> <li>BY THE WITNESS:</li> </ul>	5 6 7 8 9 10 11 12 13 14	A. There would be MR. SNELL: The jury can discern this for themselves. BY THE WITNESS: A. There would be a steady decline in their market share from approximately the high 60s to the low teens. BY MR. THORNBURGH: Q. And just above this graph it says, the last sentence, "It is anticipated that there will be at least two competitor mini-type devices launched in 2006."
7 8 9 10 11 12 13 14	<ul> <li>Q. Why is that, Doctor?</li> <li>A. Because the safety of the patient is paramount.</li> <li>Q. Do you have an opinion based on your review do you have an opinion whether or not Ethicon put patient safety before profits?</li> <li>MR. SNELL: Objection; state of mind, improper expert testimony, outside the scope.</li> <li>BY THE WITNESS: <ul> <li>A. For the TVT-Secur, yes.</li> </ul> </li> <li>BY MR. THORNBURGH: <ul> <li>Q. What's that opinion?</li> </ul> </li> </ul>	5 6 7 8 9 10 11 12 13 14	A. There would be MR. SNELL: The jury can discern this for themselves. BY THE WITNESS: A. There would be a steady decline in their market share from approximately the high 60s to the low teens. BY MR. THORNBURGH: Q. And just above this graph it says, the last sentence, "It is anticipated that there will be at least two competitor mini-type devices launched in 2006." Did I read that correctly?
7 8 9 10 11 12 13 14 15	<ul> <li>Q. Why is that, Doctor?</li> <li>A. Because the safety of the patient is paramount.</li> <li>Q. Do you have an opinion based on your review do you have an opinion whether or not Ethicon put patient safety before profits? MR. SNELL: Objection; state of mind, improper expert testimony, outside the scope.</li> <li>BY THE WITNESS: A. For the TVT-Secur, yes.</li> <li>BY MR. THORNBURGH:</li> </ul>	5 6 7 8 9 10 11 12 13 14 15	A. There would be MR. SNELL: The jury can discern this for themselves. BY THE WITNESS: A. There would be a steady decline in their market share from approximately the high 60s to the low teens. BY MR. THORNBURGH: Q. And just above this graph it says, the last sentence, "It is anticipated that there will be at least two competitor mini-type devices launched in 2006."
7 8 9 10 11 12 13 14 15 16	<ul> <li>Q. Why is that, Doctor?</li> <li>A. Because the safety of the patient is paramount.</li> <li>Q. Do you have an opinion based on your review do you have an opinion whether or not Ethicon put patient safety before profits?</li> <li>MR. SNELL: Objection; state of mind, improper expert testimony, outside the scope.</li> <li>BY THE WITNESS: <ul> <li>A. For the TVT-Secur, yes.</li> </ul> </li> <li>BY MR. THORNBURGH: <ul> <li>Q. What's that opinion?</li> </ul> </li> </ul>	5 6 7 8 9 10 11 12 13 14 15 16	A. There would be MR. SNELL: The jury can discern this for themselves. BY THE WITNESS: A. There would be a steady decline in their market share from approximately the high 60s to the low teens. BY MR. THORNBURGH: Q. And just above this graph it says, the last sentence, "It is anticipated that there will be at least two competitor mini-type devices launched in 2006." Did I read that correctly?
7 8 9 10 11 12 13 14 15 16 17 18	<ul> <li>Q. Why is that, Doctor?</li> <li>A. Because the safety of the patient is paramount.</li> <li>Q. Do you have an opinion based on your review do you have an opinion whether or not Ethicon put patient safety before profits?</li> <li>MR. SNELL: Objection; state of mind, improper expert testimony, outside the scope.</li> <li>BY THE WITNESS: <ul> <li>A. For the TVT-Secur, yes.</li> </ul> </li> <li>BY MR. THORNBURGH: <ul> <li>Q. What's that opinion?</li> <li>MR. SNELL: Same.</li> </ul> </li> </ul>	5 6 7 8 9 10 11 12 13 14 15 16 17	A. There would be MR. SNELL: The jury can discern this for themselves. BY THE WITNESS: A. There would be a steady decline in their market share from approximately the high 60s to the low teens. BY MR. THORNBURGH: Q. And just above this graph it says, the last sentence, "It is anticipated that there will be at least two competitor mini-type devices launched in 2006." Did I read that correctly? MR. SNELL: Object; leading, reading document.
7 8 9 10 11 12 13 14 15 16 17 18	<ul> <li>Q. Why is that, Doctor?</li> <li>A. Because the safety of the patient is paramount.</li> <li>Q. Do you have an opinion based on your review do you have an opinion whether or not Ethicon put patient safety before profits?</li> <li>MR. SNELL: Objection; state of mind, improper expert testimony, outside the scope.</li> <li>BY THE WITNESS: <ul> <li>A. For the TVT-Secur, yes.</li> </ul> </li> <li>BY MR. THORNBURGH: <ul> <li>Q. What's that opinion?</li> <li>MR. SNELL: Same.</li> </ul> </li> <li>BY THE WITNESS:</li> </ul>	5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. There would be MR. SNELL: The jury can discern this for themselves. BY THE WITNESS: A. There would be a steady decline in their market share from approximately the high 60s to the low teens. BY MR. THORNBURGH: Q. And just above this graph it says, the last sentence, "It is anticipated that there will be at least two competitor mini-type devices launched in 2006." Did I read that correctly? MR. SNELL: Object; leading, reading document. BY THE WITNESS: A. Yes. BY MR. THORNBURGH:
7 8 9 10 11 12 13 14 15 16 17 18 19 20	<ul> <li>Q. Why is that, Doctor?</li> <li>A. Because the safety of the patient is paramount.</li> <li>Q. Do you have an opinion based on your review do you have an opinion whether or not Ethicon put patient safety before profits? MR. SNELL: Objection; state of mind, improper expert testimony, outside the scope.</li> <li>BY THE WITNESS: A. For the TVT-Secur, yes.</li> <li>BY MR. THORNBURGH: Q. What's that opinion? MR. SNELL: Same.</li> <li>BY THE WITNESS: A. They put profits before patient safety.</li> <li>BY MR. THORNBURGH:</li> <li>Q. What's the basis for that opinion?</li> </ul>	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. There would be MR. SNELL: The jury can discern this for themselves. BY THE WITNESS: A. There would be a steady decline in their market share from approximately the high 60s to the low teens. BY MR. THORNBURGH: Q. And just above this graph it says, the last sentence, "It is anticipated that there will be at least two competitor mini-type devices launched in 2006." Did I read that correctly? MR. SNELL: Object; leading, reading document. BY THE WITNESS: A. Yes. BY MR. THORNBURGH: Q. What's the significance of that
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. Why is that, Doctor? A. Because the safety of the patient is paramount. Q. Do you have an opinion based on your review do you have an opinion whether or not Ethicon put patient safety before profits? MR. SNELL: Objection; state of mind, improper expert testimony, outside the scope. BY THE WITNESS: A. For the TVT-Secur, yes. BY MR. THORNBURGH: Q. What's that opinion? MR. SNELL: Same. BY THE WITNESS: A. They put profits before patient safety. BY MR. THORNBURGH:	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. There would be MR. SNELL: The jury can discern this for themselves. BY THE WITNESS: A. There would be a steady decline in their market share from approximately the high 60s to the low teens. BY MR. THORNBURGH: Q. And just above this graph it says, the last sentence, "It is anticipated that there will be at least two competitor mini-type devices launched in 2006." Did I read that correctly? MR. SNELL: Object; leading, reading document. BY THE WITNESS: A. Yes. BY MR. THORNBURGH:

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	Page 98		Page 100
1	outside the scope, improper expert opinion under	1	A. Yes.
2	Pennsylvania Rule 702.	2	BY MR. THORNBURGH:
3	BY MR. THORNBURGH:	3	Q. And how is that statement, if at all,
4	Q. Go ahead, Doctor.	4	important to your opinions?
5	A. If there are competitors that are on the	5	A. That the decision that was made in
6	market, they the competitors would take market	6	December of 2004 was that if the TVT X, which
7	share away from Ethicon's devices.	7	ultimately became the TVT-Secur, if it was found to
8	Q. And if you turn to it's page 4 of the	8	have a lower effectiveness as compared to the
9	attachment to Exhibit P27 or ETH.MESH.07898857, and	9	full-length TVT products, then they would not go
10	tell us what is significant to your opinions on	10	ahead with the project.
11	this page, if anything.	11	MR. SNELL: Objection.
12	A. These are this page describes	12	BY THE WITNESS:
13	critical assumptions that were made during the	13	A. And they would not launch the product.
14	planning to decide if they are going to actually go	14	MR. SNELL: Object. Sorry, Doctor.
15	ahead and make the device which ultimately became	15	THE WITNESS: It's okay.
16	the TVT-Secur. These critical assumptions, if they	16	MR. SNELL: Object. Move to strike.
17	are found to be incorrect during the design, the	17	Misstates the evidence and the document itself.
18	development and the testing of the product, would	18	Improper opinion.
19	mean that this would be a, quote, "no-go decision"	19	BY MR. THORNBURGH:
20	or they would decide against bringing this product	20	Q. Let me understand this correctly,
21	to market.	21	Doctor.
22	And this is a list of what would be, if	22	Are you telling me and the ladies and
23	these assumptions are wrong, they would not go	23	gentlemen of this jury that Ethicon that it was
24	ahead with the product.	24	Ethicon's position that if they had found or
	Dage 99		Page 101
-	Page 99		Page 101
1	MR. SNELL: Object; improper state of mind,	1	determined that the TVT-Secur was not as effective
2	MR. SNELL: Object; improper state of mind, improper expert opinion.	2	determined that the TVT-Secur was not as effective as their full-length midurethral slings like the
2 3	MR. SNELL: Object; improper state of mind, improper expert opinion. BY MR. THORNBURGH:	2 3	determined that the TVT-Secur was not as effective as their full-length midurethral slings like the TVT or the TVT-O that were already on the market
2 3 4	MR. SNELL: Object; improper state of mind, improper expert opinion.  BY MR. THORNBURGH:  Q. So, if we look at the third bullet point	2 3 4	determined that the TVT-Secur was not as effective as their full-length midurethral slings like the TVT or the TVT-O that were already on the market before they launched it, that Ethicon would not
2 3 4 5	MR. SNELL: Object; improper state of mind, improper expert opinion. BY MR. THORNBURGH: Q. So, if we look at the third bullet point on this page ending in 857 of Exhibit 1527, it	2 3 4 5	determined that the TVT-Secur was not as effective as their full-length midurethral slings like the TVT or the TVT-O that were already on the market before they launched it, that Ethicon would not launch the TVT-Secur device?
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26 (Pages 98 to 101)

THE WITNESS: I will step out of the room. I think it's probably more appropriate if 1 do. THE VIDEOCRAPHER: the time is 1-10-0 a.m. and I'm going off the video record.  WITNERUPON, be deponent exited the proceedings.)  WITNERUPON, be deponent exited the proceedings.)  WHERELIPON, the following proceedings where the proceedings will be proceedings where the proceedings will be proceedings where the other wideo record in a conference call with Justice Greenspan.'  MR. THORNBURGH: The witness is Dr. Bruce  MR. THORNBURGH: We are at this preservation deposition and with every question that I ake, and, look, I'm doing the stop sake the set questions I am a present with cornect in the matter of Ebusqu's visible, get witness and the record in a green and of her.  MR. THORNBURGH: Think you. I appreciate it. HUNTER: Okay. Just one second. I will see if I can get ahold of her.  MR. THORNBURGH: His brisis Justice  Greenspan?  JUSTICE GREENSPAN: Hello.  Page 103  JUSTICE GREENSPAN: Hello.  Page 104  MR. THORNBURGH: His brisis Justice  Greenspan:  MR. THORNBURGH: His brisis Justice  JUSTICE GREENSPAN: Hello.  MR. THORNBURGH: His brisis fustice  MR. THORNBURGH: His brisis for the skeep sessions I can be been seen preservation that I ake the standard of the deposition.  Page 105  MR. THORNBURGH: Good. I am here with defense counsel for the call, your labeling with Aylstock, Wikin, Kreis & 100 counsel for Eduicon.  MR. THORNBURGH: The reason for the call, your labeling the flow of the deposition of more defense counsel, almost every single question and with every suestion that I asked by counsel for Eduicon.  MR. THORNBURGH: The reason for the call, your labeling of the following process of the seed of the follow.  JUSTICE GREENSPAN: This is she.  MR. THORNBURGH: His brisise Greenspan. His Burt asked by counsel for Eduicon.  MR. THORNBURGH: The reason for the ca		Page 102		Page 104
think it's probably more appropriate if I do.  THE VIDEOGRAPHER: The time is 11:06 a.m. and The going off the video record.  (WHEREUPON, the deponent exited the proceedings.) (WHEREUPON, Bobby (Brad) Bradford, Esq. entered the proceedings.) (WHEREUPON, Bobby (Brad) Bradford, Esq. entered the proceedings.) (WHEREUPON, Bobby (Brad) Bradford, Esq. entered the proceedings.)  WHEREUPON, Bradford, Esq. entered the proceedings.  WHEREUPON, Bradford, Esq. entered the entered withs site in the processor of the proceedings.  WHEREUPON, Bradford, Esq. entered the proceedings.  WHEREUPON, Bradford, Esq. entered the proceedings.  WHEREUPON, Bradford, Esq. entered the entered withs site in the processor of the proceedings.  WHEREUPON, Bradford, Esq. entered with entered with entered	1	THE WITNESS: I will step out of the room. I	1	JUSTICE GREENSPAN: Right now?
THE VIDEOGRAPHER: The time is 11:06 a.m. and I'm going off the video record.  WHEREUPON, the deponent exited the proceedings.)  (WHEREUPON, Bobby (Brad) Bradford, Esq. entered the proceedings.)  (WHEREUPON, the following proceedings were had off the video record in a conference call with Justice Greenspan:)  HUNTER: Thank you for calling JAMS. This is Hunter. My name is Dan Thornburgh. I'm here in a deposition with defense coursed in the matter of Fbaugh vs. Enhicon and Jams and the proceedings.)  MR. THORNBURGH: Hi, Hunter. My name is Dan Thornburgh. I'm here in a deposition with defense coursed in the matter of Fbaugh vs. Enhicon and Jams an	2	_	2	MR. THORNBURGH: In a deposition right now in
4 Johnson & Johnson Lis another TVT-Secur case. 5 (WHEREUPON, the deponent exited the proceedings.) 6 (WHEREUPON, Bobby (Brad) Bradford, Beach case.) 7 (WHEREUPON, Bobby (Brad) Bradford, Beach case.) 8 Esq. entered the proceedings.) 9 (WHEREUPON, the following 9 wines? What's his position? 10 proceedings were had off the video 11 record in a conference call with 12 Justice Greenspan:) 11 proceeding were had off the video 12 more off and on ofference call with 13 Justice Greenspan: 14 Huntre: 15 MR. THORNBURGH: Hi, Hunter, My name is Dant 16 Thornburgh. I'm here in a deposition with defense 17 course in the matter of Ebaugh vs. Ethicon and 18 Johnson a Johnson and we have kind of a discovery 19 issue or dispute that If like to, if possible, get 20 sone guidance from Judge Greenspan. 21 HUNTER: Okay, Just one second. I will see 17 ILUNTER: Okay, Just one second. I will see 18 ILUNTER: Okay, Just one second. I will see 19 ILUNTER:	3		3	
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	Page 106		Page 108
1	JUSTICE GREENSPAN: Okay.	1	But if the Plaintiffs' counsel just
2	MR. SNELL: in his prior de bene esse.	2	wants me to object, then I will do that. That's
3	JUSTICE GREENSPAN: What's going on here? Why	3	fine.
4	can't you just make an objection and leave it at	4	JUSTICE GREENSPAN: I think you should put the
5	that?	5	basis as sort of as you explained it to me, I am
6	MR. SNELL: Well, one, Justice, that's not how	6	sure you will do a beautiful job putting it on the
7	we did this. This is a trial de bene esse	7	record. But once you do that, unless there is an
8	deposition. This is not some discovery deposition.	8	objection based on something different, that
9	I took his de bene esse TVT deposition,	9	objection will, you know there can be an
10	and I made these similar type objections when there	10	agreement that just placing the objection will
11	was improper questioning as to expert subject	11	preserve that as the basis.
12	matter.	12	MR. THORNBURGH: Yeah, your Honor, and this is
13	To put things into context, Justice	13	Dan Thornburgh.
14	Greenspan, I'm not objecting to every question but	14	I've already agreed that all he has to
15	when the Plaintiffs' counsel is asking	15	do is object. He doesn't have to give a basis and
16	Dr. Rosenzweig "What was Ethicon thinking" and	16	it won't be a waiver of any objection later on. I
17	"Would it be right for a manufacturer to ever think	17	have already agreed to that with the exception of
18	this," that's all improper expert subject matter	18	leading, because I need to know, if I asked it
19	and state of mind.	19	improperly, I need to know that I need to go back
20	So, the majority of my opinions have	20	and correct the answer.
21	been on state of mind, expert improper opinion; and	21	But all he's got to do is say
22	this is basically an exam that's not comporting	22	"Objection." We can handle the basis for the
23	with the Pennsylvania rules from my perspective.	23	objection later on so that it doesn't interrupt the
24	So, that's where these objections are	24	flow of this deposition.
	Page 107		Page 109
1	coming from. Plaintiffs' counsel reading sentences	1	JUSTICE GREENSPAN: Okay. Is that okay, Burt?
2	from a document.	2	Can we agree there?
3	JUSTICE GREENSPAN: Why don't you Burt,	3	MR. SNELL: Yeah, yes, I guess we can, your
4	Burt, why don't you just say, "I have a standing	4	Honor. I just really have a real concern about
5	objection based on the following." Put it on the	5	waiver issues.
6	record and then, you know, as the deposition	6	MR. THORNBURGH: I am telling you.
7	continues on, just make your you don't have		
		7	JUSTICE GREENSPAN: Okay. You may have a
8	to unless it's something very different like	8	valid, very valid basis to object. But, you know,
9	it's leading or something like that where you can	8 9	valid, very valid basis to object. But, you know, as long as you state it on the record and, you
9 10	it's leading or something like that where you can say "Objection; leading," why don't you just say	8 9 10	valid, very valid basis to object. But, you know, as long as you state it on the record and, you know, it's going to be preserved.
9 10 11	it's leading or something like that where you can say "Objection; leading," why don't you just say "Objection" and that objection will hold for your	8 9 10 11	valid, very valid basis to object. But, you know, as long as you state it on the record and, you know, it's going to be preserved.  MR. SNELL: Okay.
9 10 11 12	it's leading or something like that where you can say "Objection; leading," why don't you just say "Objection" and that objection will hold for your standing objection.	8 9 10 11 12	valid, very valid basis to object. But, you know, as long as you state it on the record and, you know, it's going to be preserved.  MR. SNELL: Okay.  JUSTICE GREENSPAN: Just state that "When I
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28 (Pages 106 to 109)

	Page 110		Page 112
1	I think the best way to handle this is	1	including violating PA procedure, with the
2	he can just object without giving a basis with the	2	exception of leading. I'll tell Mr. Thornburgh if
3	exception of leading, and it's not won't be a	3	it's actually leading as the basis. That's the
4	waiver of his objection if he doesn't give a basis.	4	agreement I guess.
5	MR. BRADFORD: Of any basis.	5	MR. THORNBURGH: Yes.
6	JUSTICE GREENSPAN: That's generally	6	MR. SNELL: Okay.
7	generally that's true unless a basis is requested,	7	JUSTICE GREENSPAN: Okay. Is that the
8	unless the judge, and usually it's in the trial,	8	agreement? Okay.
9	the judge asks for a basis.	9	MR. THORNBURGH: Yes.
10	MR. SNELL: That's what I am doing, your	10	JUSTICE GREENSPAN: Make sure that goes on the
11	Honor, because this is a trial deposition just like	11	record.
12	Dr. Rosenzweig is before a jury. So, that was	12	MR. THORNBURGH: It is. And thank you so
13	that's my heightened sense. Obviously if it was a	13	much. Thank you so much, your Honor. Appreciate
14	discovery depo, that's different.	14	it.
15	And your Honor has seen the types of	15	MR. SNELL: Agreed. Thank you for your
16	objections I made in his first trial de bene esse	16	guidance.
17	deposition. They are like this: Objection;	17	JUSTICE GREENSPAN: Okay. That's fine. Okay.
18	improper subject matter of an expert, you know,	18	MR. SNELL: Have a great day.
19	lacks facts or bases, state of mind. That's what	19	JUSTICE GREENSPAN: Very good. Thank you.
20	I'm doing.	20	MR. SNELL: Bye.
21	MR. THORNBURGH: The difference here than a	21	JUSTICE GREENSPAN: Bye.
22	trial deposition is obviously we don't have a judge	22	(WHEREUPON, the conference call with
23	here, but what I'm what we are going to have is	23	Justice Greenspan was concluded.)
24	we are going to have arguments in front of probably	24	Justice Greenspair was concluded.)
	we are going to have arguments in front of probably		
	Page 111		Page 113
1	Page 111 your Honor or before the trial judge on this, you	1	Page 113 (WHEREUPON, the following further
1 2		1 2	
	your Honor or before the trial judge on this, you		(WHEREUPON, the following further
2	your Honor or before the trial judge on this, you know, the admissibility of these questions and	2	(WHEREUPON, the following further proceedings were had off the video
2	your Honor or before the trial judge on this, you know, the admissibility of these questions and answers and what I'm saying is he is not going to	2 3	(WHEREUPON, the following further proceedings were had off the video record:)
2 3 4	your Honor or before the trial judge on this, you know, the admissibility of these questions and answers and what I'm saying is he is not going to waive an objection if he doesn't give a basis.	2 3 4	(WHEREUPON, the following further proceedings were had off the video record:)  MR. SNELL: If it's leading, I got to tell you
2 3 4 5	your Honor or before the trial judge on this, you know, the admissibility of these questions and answers and what I'm saying is he is not going to waive an objection if he doesn't give a basis.  That will be taken up in front of your	2 3 4 5	(WHEREUPON, the following further proceedings were had off the video record:)  MR. SNELL: If it's leading, I got to tell you leading. Otherwise I just object.
2 3 4 5 6	your Honor or before the trial judge on this, you know, the admissibility of these questions and answers and what I'm saying is he is not going to waive an objection if he doesn't give a basis.  That will be taken up in front of your Honor or in front of the Trial Court prior to the	2 3 4 5 6	(WHEREUPON, the following further proceedings were had off the video record:)  MR. SNELL: If it's leading, I got to tell you leading. Otherwise I just object.  MR. BRADFORD: Leading, you know, if
2 3 4 5 6 7	your Honor or before the trial judge on this, you know, the admissibility of these questions and answers and what I'm saying is he is not going to waive an objection if he doesn't give a basis.  That will be taken up in front of your Honor or in front of the Trial Court prior to the trial. The problem with the way it's going on	2 3 4 5 6 7	(WHEREUPON, the following further proceedings were had off the video record:)  MR. SNELL: If it's leading, I got to tell you leading. Otherwise I just object.  MR. BRADFORD: Leading, you know, if there's
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2 3 4 5 6 7 8 9 10 11 12 13	your Honor or before the trial judge on this, you know, the admissibility of these questions and answers and what I'm saying is he is not going to waive an objection if he doesn't give a basis.  That will be taken up in front of your Honor or in front of the Trial Court prior to the trial. The problem with the way it's going on right now is it's interrupting the flow of the questions and answers.  JUSTICE GREENSPAN: Okay. Well, let's try to get through it so that the interruptions are, you know, as minimal as possible.  MR. SNELL: Okay.	2 3 4 5 6 7 8 9 10 11 12 13	(WHEREUPON, the following further proceedings were had off the video record:)  MR. SNELL: If it's leading, I got to tell you leading. Otherwise I just object.  MR. BRADFORD: Leading, you know, if there's  MR. SNELL: No, no, no. Don't come in here no, Brad.  MR. BRADFORD: To the form of the question, leading, compound. If there is a form problem with the question that can be fixed, that's different than a substantive objection. Leading, compound,
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	5 114		D 116
	Page 114		Page 116
1	are changing? I'm not changing that.	1	shorter mesh was not found to have equivalent
2	MR. THORNBURGH: It's okay. Just it's to	2	efficacy, that would lead to a no-go decision.
3	leading. I don't care.	3	BY MR. THORNBURGH:
4	I don't ask compound questions.	4	Q. Equivalent efficacy to what products?
5	(WHEREUPON, the deponent entered the	5	A. The full-length TVT and TVT-O products.
6	proceedings.)	6	Q. Okay. In layman in layperson terms,
7	(WHEREUPON, the following	7	what does it mean to what does "equivalent
8	proceedings were had on the video	8	efficacy" mean?
9	record:)	9	A. If that means that it works to treat
10	THE VIDEOGRAPHER: The time is 11:20 a.m. and	10	the condition, which is incontinence, to about the
11	we're back on the video record.	11	same level.
12	BY MR. THORNBURGH:	12	Q. Okay. So, if if it was determined
13	Q. Doctor, before we went off the record,	13	before they launched the product that the TVT-Secur
14	we were discussing Exhibit P1527 and we were on	14	did not work as well as the TVT Retropubic or the
15	page 4 of the document that was attached, the	15	TVT-Obturator, the TVT-O, what is your
16	charter agreement, Bates number ending in 857.	16	understanding as to what this no-go decision would
17	Okay?	17	require?
18	A. Yes.	18	MR. SNELL: Object.
19	Q. Are you there? And we were discussing	19	BY THE WITNESS:
20	the "Critical Assumptions" section, is that	20	A. That they not launch the product.
21	correct?	21	BY MR. THORNBURGH:
22	A. Yes.	22	Q. And is that an appropriate decision to
23	Q. Okay. And what does the critical	23	make under such circumstances?
24	what does that sentence under "Critical	24	MR. SNELL: Object.
1	Page 115	1	Page 117 BY THE WITNESS:
2	Assumptions" say? MR. SNELL: Object.	2	A. Yes.
3	BY THE WITNESS:	3	BY MR. THORNBURGH:
4	A. "What are the assumptions about the		
7	A. What are the assumptions about the	1 /	And do you know whother or not and
_		4 5	Q. And do you know whether or not, and
5 6	project, which if incorrect, could result in a	5	we'll talk about it in greater detail, do you know
6	project, which if incorrect, could result in a no-go decision?"	5 6	we'll talk about it in greater detail, do you know whether or not Ethicon ever determined before they
6 7	project, which if incorrect, could result in a no-go decision?" BY MR. THORNBURGH:	5 6 7	we'll talk about it in greater detail, do you know whether or not Ethicon ever determined before they launched the TVT-Secur product that the TVT-Secur
6 7 8	project, which if incorrect, could result in a no-go decision?" BY MR. THORNBURGH: Q. And what is the first bullet point that	5 6 7 8	we'll talk about it in greater detail, do you know whether or not Ethicon ever determined before they launched the TVT-Secur product that the TVT-Secur was less effective than the other devices that they
6 7 8 9	project, which if incorrect, could result in a no-go decision?"  BY MR. THORNBURGH:  Q. And what is the first bullet point that was a critical assumption that if incorrect would	5 6 7 8 9	we'll talk about it in greater detail, do you know whether or not Ethicon ever determined before they launched the TVT-Secur product that the TVT-Secur was less effective than the other devices that they had in their playground such as the TVT Retropubic
6 7 8 9 10	project, which if incorrect, could result in a no-go decision?"  BY MR. THORNBURGH:  Q. And what is the first bullet point that was a critical assumption that if incorrect would result in a no-go decision?	5 6 7 8 9	we'll talk about it in greater detail, do you know whether or not Ethicon ever determined before they launched the TVT-Secur product that the TVT-Secur was less effective than the other devices that they had in their playground such as the TVT Retropubic and the TVT-Obturator?
6 7 8 9 10 11	project, which if incorrect, could result in a no-go decision?"  BY MR. THORNBURGH:  Q. And what is the first bullet point that was a critical assumption that if incorrect would result in a no-go decision?  A. "Shorter"	5 6 7 8 9 10 11	we'll talk about it in greater detail, do you know whether or not Ethicon ever determined before they launched the TVT-Secur product that the TVT-Secur was less effective than the other devices that they had in their playground such as the TVT Retropubic and the TVT-Obturator?  MR. SNELL: Object.
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	project, which if incorrect, could result in a no-go decision?"  BY MR. THORNBURGH:  Q. And what is the first bullet point that was a critical assumption that if incorrect would result in a no-go decision?  A. "Shorter"  MR. SNELL: Object.  BY THE WITNESS:  A. "Shorter mesh implanted will provide equivalent efficacy compared to current mesh length and position in both the retropubic and obturator direction."  BY MR. THORNBURGH:  Q. And what's your understanding of that that assumption that if incorrect would result in a no-go decision?  MR. SNELL: Object.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	we'll talk about it in greater detail, do you know whether or not Ethicon ever determined before they launched the TVT-Secur product that the TVT-Secur was less effective than the other devices that they had in their playground such as the TVT Retropubic and the TVT-Obturator?  MR. SNELL: Object. BY THE WITNESS:  A. Yes. BY MR. THORNBURGH: Q. And what was their what was the finding? A. That it was less effective. Q. And, so, based on this critical assumption, what could Ethicon have done when they determined that?  A. Not launch the product. Q. And do you have an opinion whether or
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	project, which if incorrect, could result in a no-go decision?"  BY MR. THORNBURGH:  Q. And what is the first bullet point that was a critical assumption that if incorrect would result in a no-go decision?  A. "Shorter"  MR. SNELL: Object. BY THE WITNESS:  A. "Shorter mesh implanted will provide equivalent efficacy compared to current mesh length and position in both the retropubic and obturator direction."  BY MR. THORNBURGH:  Q. And what's your understanding of that that assumption that if incorrect would result in a no-go decision?	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	we'll talk about it in greater detail, do you know whether or not Ethicon ever determined before they launched the TVT-Secur product that the TVT-Secur was less effective than the other devices that they had in their playground such as the TVT Retropubic and the TVT-Obturator?  MR. SNELL: Object. BY THE WITNESS:  A. Yes. BY MR. THORNBURGH: Q. And what was their what was the finding?  A. That it was less effective. Q. And, so, based on this critical assumption, what could Ethicon have done when they determined that?  A. Not launch the product.

30 (Pages 114 to 117)

	Page 118		Page 120
1	lacked equivalent efficacy to the TVT Retropubic or	1	laser-cut, rigid mesh, the sharp arrow tip
2	TVT-Obturator products?	2	introducer and the fleece tips that would hold the
3	A. Yes, I have an opinion.	3	sling in place to treat stress urinary
4	Q. What's that opinion?	4	incontinence, those had never been used before but
5	A. That they should not have launched it.	5	they are going to claim that it is similar to the
6	Q. If we turn to the page ending in	6	products that had already been on the market.
7	ETH.MESH.07898861 of Exhibit P1527, could you tell	7	Q. And is it appropriate for a company to
8	us what part of this page is important to your	8	make claims that are unproven?
9	opinions?	9	MR. SNELL: Object.
10	MR. SNELL: Object; leading.	10	BY THE WITNESS:
11	BY MR. THORNBURGH:	11	A. No.
12	Q. What's the next page that you'd like to	12	BY MR. THORNBURGH:
13	discuss with the ladies and gentlemen of the jury?	13	Q. Why is that?
14	A. The it's marked as page 8 in the	14	Let me ask a better question.
15	document.	15	Do you have an opinion whether or not it
16	Q. And what's the significance of this	16	is appropriate for a medical device company to make
17	page with respect to your opinions in this case?	17	claims about their products that are not proven?
18	A. There is a discussion about how the	18	MR. SNELL: Same objection.
19	TVT X, which ultimately became the TVT-Secur, would	19	BY THE WITNESS:
20	prevent the erosion of the pricing of the current	20	A. I do have an opinion.
21	slings and would help prevent loss of market share,	21	BY MR. THORNBURGH:
22	but that some of the current users of their	22	Q. What's that opinion?
23	products would then switch to using the TVT-Secur.	23	A. It is not appropriate.
24	Q. Okay. And if we is there any other	24	Q. Why not?
	Page 119		Page 121
1	section on this page that you'd like to discuss	1	A. Because one should make claims about a
2	with the jury?	2	product that is based on on evidence derived
3	A. Yes.	3	from clinical testing.
4	Q. And what's that?	4	Q. Do you have an opinion about whether or
5	A. That they are going to state that the	5	not Ethicon or at least Ethicon's employees had an
6	product characteristics or claims about the product	6	understanding that the TVT-Secur was different, a
7	will be similar to the current TVT products.	7	different device than the TVT Retropubic or the
8	Q. And if we just pull up that paragraph	8	TVT-Obturator?
9	that you're at. Are you at the second-to-last	9	MR. SNELL: Objection.
10	bolded section on this page?	10	BY THE WITNESS:
11	A. The last bolded section, "What claims	11	A. Yes.
12	will we make for the proposed solution?"	12	BY MR. THORNBURGH:
13	Q. Okay. And it says, "Product claims will	13	Q. And what's that opinion?
	be similar to our classic TVT products, but we will	14	A. That they knew it was a different
14		1	•
14 15	add additional claims of being less invasive, which	15	device.
	add additional claims of being less invasive, which should not require a study to validate."	15 16	Q. And what's the basis for that opinion?
15			
15 16	should not require a study to validate."	16	Q. And what's the basis for that opinion?
15 16 17	should not require a study to validate."  Did I read that correctly?	16 17	<ul><li>Q. And what's the basis for that opinion?</li><li>A. Internal documents and deposition</li></ul>
15 16 17 18	should not require a study to validate."  Did I read that correctly?  A. Yes.	16 17 18	<ul><li>Q. And what's the basis for that opinion?</li><li>A. Internal documents and deposition testimony.</li></ul>
15 16 17 18 19	should not require a study to validate."  Did I read that correctly?  A. Yes.  Q. And how is that important, if at all, to your opinions?	16 17 18 19	<ul><li>Q. And what's the basis for that opinion?</li><li>A. Internal documents and deposition testimony.</li><li>Q. And will we discuss some of those</li></ul>
15 16 17 18 19 20	should not require a study to validate."  Did I read that correctly?  A. Yes.  Q. And how is that important, if at all, to	16 17 18 19 20	<ul><li>Q. And what's the basis for that opinion?</li><li>A. Internal documents and deposition testimony.</li><li>Q. And will we discuss some of those documents today?</li></ul>
15 16 17 18 19 20 21	should not require a study to validate."  Did I read that correctly?  A. Yes.  Q. And how is that important, if at all, to your opinions?  A. Well, they're going to state that the	16 17 18 19 20 21	<ul> <li>Q. And what's the basis for that opinion?</li> <li>A. Internal documents and deposition testimony.</li> <li>Q. And will we discuss some of those documents today?</li> <li>A. Yes.</li> </ul>

	Page 122		Page 124
1	Q. Is that ETH.MESH ending in 868 of	1	BY THE WITNESS:
2	Exhibit P1527?	2	A. Yes.
3	A. That is correct.	3	BY MR. THORNBURGH:
4	Q. And what section or what section of this	4	Q. Let me ask a better way.
5	page do you want to discuss?	5	If Ethicon, based on your review of the
6	A. It's called "Risk Assessment." It is	6	documents, including this document in particular,
7	the "Assumptions to Achieve Commitment," commitment	7	if Ethicon had performed a pre-market study, in
8	meaning the commitment to proceed with the with	8	other words, a study before they launched the
9	the project.	9	TVT-Secur, that determined that there were issues
10	Q. Okay. And how is or what is significant	10	with the device in terms of its design
11	on this page with respect to the opinions you are	11	characteristics, what would occur?
12	offering?	12	A. Those
13	MR. SNELL: Object. Go ahead.	13	MR. SNELL: Same objection.
14	BY THE WITNESS:	14	BY THE WITNESS:
15	A. That one of the assumptions is that	15	A. Those design characteristics should be
16	there will be no significant design changes at the	16	changed to make the device either safer or more
17	start of a study that is being planned to be done	17	effective.
18	before the device is marketed.	18	BY MR. THORNBURGH:
19	BY MR. THORNBURGH:	19	Q. And what would how would that impact,
20	Q. Okay. And and what's the next bullet	20	if at all, the Ethicon's timeline for launching
21	point you'd like to discuss, if any?	21	the product?
22	A. That the timeline assumes that there	22	A. It would make the timeline longer. The
23	will be no design changes and the start of the	23	current timeline assumes that they that the
24	study assumes that there will be no design changes	24	pre-market study will find neither an effectiveness
	D 102		
	Page 123		Page 125
1	Page 123	1	Page 125
1 2	in the characteristics of the device, that the	1 2	issue or a safety issue that would require changes
2	in the characteristics of the device, that the design is frozen meaning that there will be no	2	issue or a safety issue that would require changes in the design characteristics.
2	in the characteristics of the device, that the design is frozen meaning that there will be no changes made to the device.	2 3	issue or a safety issue that would require changes in the design characteristics.  Q. And we had looked at a number of
2 3 4	in the characteristics of the device, that the design is frozen meaning that there will be no changes made to the device.  Q. All right. Let me let's look at the	2 3 4	issue or a safety issue that would require changes in the design characteristics.  Q. And we had looked at a number of sections of this document, including a section that
2	in the characteristics of the device, that the design is frozen meaning that there will be no changes made to the device.  Q. All right. Let me let's look at the second bullet point. It says, "Timeline assumes	2 3	issue or a safety issue that would require changes in the design characteristics.  Q. And we had looked at a number of sections of this document, including a section that had discussed Ethicon's desire to become first to
2 3 4 5	in the characteristics of the device, that the design is frozen meaning that there will be no changes made to the device.  Q. All right. Let me let's look at the second bullet point. It says, "Timeline assumes results of the pre-market study does not require	2 3 4 5	issue or a safety issue that would require changes in the design characteristics.  Q. And we had looked at a number of sections of this document, including a section that had discussed Ethicon's desire to become first to market, the mini-sling. Do you recall that
2 3 4 5 6 7	in the characteristics of the device, that the design is frozen meaning that there will be no changes made to the device.  Q. All right. Let me let's look at the second bullet point. It says, "Timeline assumes results of the pre-market study does not require design changes."	2 3 4 5 6 7	issue or a safety issue that would require changes in the design characteristics.  Q. And we had looked at a number of sections of this document, including a section that had discussed Ethicon's desire to become first to market, the mini-sling. Do you recall that MR. SNELL: Objection.
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#### Page 126 Page 128 1 BY MR. THORNBURGH: 1 What's your understanding of that 2 Q. And how would that -- a negative finding 2 critical assumption and how does that, if at all, 3 3 in their pre-market study that required a design support your opinions? 4 change, how would that negative result and design 4 A. Well, that -- this document shows that 5 change potentially impact Ethicon's market share? 5 or this document describes that as of December of 6 MR. SNELL: Object. 6 2004 it was a new discovery that they would need to 7 7 BY MR. THORNBURGH: do a clinical trial prior to the launch of the 8 Q. Based on your review of these documents? 8 product. 9 9 MR. SNELL: Object. Q. And it says, "Pre-Market study outcomes 10 BY THE WITNESS: 10 that drive design changes." 11 11 Did I read that correctly? A. It would negatively impact their market 12 share as being first to market and is important to 12 A. Yes. Q. And how, if at all, does that critical 13 13 establish a market share. 14 BY MR. THORNBURGH: 14 assumption support your opinions? 15 Q. Okay. Would Ethicon, based on your 15 A. Well, this supports my opinions that a 16 16 review of this document or these documents, lose pre-market study is important to test the safety 17 17 money if -- if the pre-market study resulted in a and efficacy of a product and in -- and, 18 negative finding that required a design change that 18 particularly, the design characteristics of that 19 19 product that would make it either less effective or resulted in a delay of launching the product which 20 resulted in a competitor bringing their product to 20 less safe and that a pre-market study that 21 21 the market first? determines if there are design characteristics that 2.2 MR. SNELL: Object. 22 make it unsafe or less effective would then drive 23 BY THE WITNESS: 23 changes in those design characteristics to make it 24 A. Yes, they would lose money. 24 more effective and more safe. Page 127 Page 129 BY MR. THORNBURGH: 1 Q. And is -- let me ask you this question: 1 2 Q. Is there any other section or page of 2 Do you have an opinion whether or not companies who 3 3 this exhibit that you'd like to discuss? should perform adequate testing -- strike that. 4 A. It is page 17 or ETH.MESH ending in 4 Do you have an opinion whether or not 5 5 8870. Ethicon should have performed adequate pre-market 6 6 studies before launching the TVT-Secur product? Q. Okay. And what is significant on this 7 page of Exhibit P1527? 7 A. Yes, I have an opinion. 8 A. It describes critical assumptions that 8 Q. What's that opinion? 9 are fundamental for the project to be successful 9 A. They should have performed testing. 10 but outside the control of the team that is 10 Q. And if Ethicon had performed pre-market 11 responsible for the design, development and testing 11 human studies and found that the product lacked 12 12 of the device characteristics. efficacy or had safety issues, do you have an 13 Q. And what section are you speaking about 13 opinion what Ethicon should have done? 14 on this page? 14 MR. SNELL: Objection. 15 A. It is under "Critical Assumptions." 15 BY THE WITNESS: 16 Q. And it says, "Critical Assumptions. 16 A. Yes, either not launched the product or 17 Identify critical assumptions fundamental to 17 defined what are those design characteristics that 18 success but outside the control of the team." 18 either are leading to less efficacy or less -- or 19 And there is a list of those critical 19 impaired safety and changed those design 20 assumptions, is that correct? 20 characteristics to improve efficacy and improve 21 A. Correct. 21 safety. 22 Q. Okay. And No. 2 says, "New discoveries 22 BY MR. THORNBURGH: 23 drive the need for a clinical trial prior to 23 Q. And why, if at all, is that important? 24 launch." 24 A. It's important because that impacts

	Page 130		Page 132
1	patient safety.	1	pain with intercourse.
2	Q. What do you mean it "impacts patient	2	Q. What's the basis for that opinion,
3	safety"?	3	Doctor?
4	A. Well, if it if there are	4	A. The medical literature.
5	characteristics of the device that are unreasonably	5	Q. And will we will we review some of
6	unsafe, then the patient is exposed to design	6	those medical literature today?
7	characteristics that are unreasonably unsafe. It	7	MR. SNELL: Objection; leading.
8	leads to complications.	8	BY MR. THORNBURGH:
9	A less effective device means that the	9	Q. Let me say it a better way. We'll
10	patient is not treated for stress urinary	10	discuss some of those later on.
11	incontinence and then would require additional	11	Is it fair to say that we will discuss
12	treatment or additional surgery to treat their	12	some of those supporting
13	remaining or recurrent stress urinary incontinence.	13	A. That is
14	Q. What's the next exhibit that you'd like	14	Q medical literature later today?
15	to discuss?	15	MR. SNELL: Objection; leading.
16	A. It is marked P0732. It is an e-mail	16	BY THE WITNESS:
17	between Ethicon employees, including Dan Smith,	17	A. That has been described in my prior
18	lead engineer and patent holder, one of the patent	18	testimony, yes.
19	holders for the TVT-Secur. It's from December 14,	19	I'd also like to point out that this
20	2004, and it is describing the comparison between	20	document also found that at one inch of stress,
21	laser-cut mesh and mechanical-cut mesh.	21	laser-cut mesh was three times stiffer than
22	Q. Okay. And how does this Exhibit 732	22	mechanical-cut mesh.
23	support your opinions, if at all?	23	However, attached to this document is a
24	A. It supports my opinions that laser-cut	24	comparison with other competitors which showed that
24	A. It supports my opinions that faser-cut	21	comparison with other competitors which showed that
	Page 131		Page 133
1	mesh is three times stiffer than mechanical-cut	1	laser-cut mesh was less stiff and establishing a
2	mesh, making the short TVT-Secur stiffer than the	2	lower resistance load to competitor mesh.
3	full-length TVT devices that were on the market in	3	Q. Okay. And is that important at all in
4	2004 through the time of launch in 2006.	4	your opinions?
5	Q. Does that matter?	5	A. Yes. Those other slings are have
6	MR. SNELL: Objection.	6	design characteristics that make them unreasonably
7			
,	BY MR. THORNBURGH:	7	unsafe.
8	BY MR. THORNBURGH:  Q. Do you have an opinion whether or not it	7 8	unsafe. Q. So, do you have an opinion whether or
_		l _	
8	Q. Do you have an opinion whether or not it matters that the TVT laser-cut mesh was more stiff than laser-cut mesh?	8	Q. So, do you have an opinion whether or not because of the mesh characteristics or the stiffness of the TVT laser-cut mesh, whether or not
8 9	Q. Do you have an opinion whether or not it matters that the TVT laser-cut mesh was more stiff than laser-cut mesh?  MR. SNELL: Objection.	8 9 10 11	Q. So, do you have an opinion whether or not because of the mesh characteristics or the stiffness of the TVT laser-cut mesh, whether or not those characteristics make the TVT laser-cut
8 9 10	Q. Do you have an opinion whether or not it matters that the TVT laser-cut mesh was more stiff than laser-cut mesh?  MR. SNELL: Objection. BY MR. THORNBURGH:	8 9 10 11 12	Q. So, do you have an opinion whether or not because of the mesh characteristics or the stiffness of the TVT laser-cut mesh, whether or not
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8 9 10 11 12	Q. Do you have an opinion whether or not it matters that the TVT laser-cut mesh was more stiff than laser-cut mesh?  MR. SNELL: Objection. BY MR. THORNBURGH:  Q. Does that is there let me ask a better question.	8 9 10 11 12	Q. So, do you have an opinion whether or not because of the mesh characteristics or the stiffness of the TVT laser-cut mesh, whether or not those characteristics make the TVT laser-cut devices unreasonably unsafe as well?
8 9 10 11 12 13	<ul> <li>Q. Do you have an opinion whether or not it matters that the TVT laser-cut mesh was more stiff than laser-cut mesh?</li> <li>MR. SNELL: Objection.</li> <li>BY MR. THORNBURGH:</li> <li>Q. Does that is there let me ask a better question.</li> <li>Do you have an opinion whether or not</li> </ul>	8 9 10 11 12 13 14 15	Q. So, do you have an opinion whether or not because of the mesh characteristics or the stiffness of the TVT laser-cut mesh, whether or not those characteristics make the TVT laser-cut devices unreasonably unsafe as well?  MR. SNELL: Object. BY THE WITNESS:  A. Yes.
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8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. Do you have an opinion whether or not it matters that the TVT laser-cut mesh was more stiff than laser-cut mesh?  MR. SNELL: Objection.  BY MR. THORNBURGH:  Q. Does that is there let me ask a better question.  Do you have an opinion whether or not there is any clinical significance to a having a stiffer mesh device?  A. Yes. A stiffer mesh device is a design characteristic that increases harm to women.  Stiffness of the mesh increases the chronic inflammation, chronic foreign body reaction, the degree of scar-plating that occurs which results in the injuries, mesh erosion, mesh contraction, which	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. So, do you have an opinion whether or not because of the mesh characteristics or the stiffness of the TVT laser-cut mesh, whether or not those characteristics make the TVT laser-cut devices unreasonably unsafe as well?  MR. SNELL: Object. BY THE WITNESS:  A. Yes.  MR. SNELL: Go ahead. BY MR. THORNBURGH:  Q. What's that opinion?  A. That it the laser cutting makes the TVT-Secur, the short TVT-Secur mesh unreasonably unsafe due to the stiffness and rigidity associated with the short mesh and compounded by the laser cutting of the short mesh.
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Do you have an opinion whether or not it matters that the TVT laser-cut mesh was more stiff than laser-cut mesh?  MR. SNELL: Objection.  BY MR. THORNBURGH:  Q. Does that is there let me ask a better question.  Do you have an opinion whether or not there is any clinical significance to a having a stiffer mesh device?  A. Yes. A stiffer mesh device is a design characteristic that increases harm to women.  Stiffness of the mesh increases the chronic inflammation, chronic foreign body reaction, the degree of scar-plating that occurs which results in	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. So, do you have an opinion whether or not because of the mesh characteristics or the stiffness of the TVT laser-cut mesh, whether or not those characteristics make the TVT laser-cut devices unreasonably unsafe as well?  MR. SNELL: Object. BY THE WITNESS:  A. Yes.  MR. SNELL: Go ahead. BY MR. THORNBURGH:  Q. What's that opinion?  A. That it the laser cutting makes the TVT-Secur, the short TVT-Secur mesh unreasonably unsafe due to the stiffness and rigidity associated with the short mesh and compounded by the laser

#### Page 134 Page 136 1 to discuss with the ladies and gentlemen of the product is designed, developed and tested and the 1 2 2 steps taken to validate the design and development 3 3 A. It's ETH.MESH ending in 9108. and testing of the product. 4 Q. Is there a P number, an Exhibit number? 4 Q. And have you reviewed the TVT 5 A. P1318. 5 internal -- strike that. 6 MR. SNELL: While you are looking, I'm just 6 Have you reviewed the internal Ethicon 7 7 going to object on P1527. That was not on the company documents concerning the design validation 8 doctor's reliance list. So, I move to strike any 8 of the TVT-Secur? 9 9 and all testimony about that exhibit. A. Correct. 10 MR. THORNBURGH: Hold on a second. P what? 10 O. And is this one of those documents? 11 The last exhibit? I'm sorry. P1318? 11 A. Yes. 12 MR. SNELL: P1527. 12 Q. And what part of this e-mail string do 13 MR. THORNBURGH: 1527. What is that one? The 13 you want to discuss that support your opinions? 14 charter agreement? 14 A. Well, this document is discussing one of 15 15 MR. SNELL: Yes. the design processes, which is the -- included a 16 MR. THORNBURGH: He's testified about the 16 cadaver or series of cadaver labs where doctors and 17 17 charter agreement in multiple trials. I think it's surgeons were invited to come and place the device 18 on his reliance list, as well as the deposition 18 in cadavers. 19 testimony of people who have testified about that 19 And there was a degree of difficulty, 20 document like Renee Selman and he disclosed all 20 which is described in the beginning of the e-mail 21 21 exhibits with respect to those witnesses that were string, of -- that these doctors were having 22 on -- attached to those transcripts as you guys 22 trouble with the introducers and passing the device 23 23 know. in a certain -- in the appropriate place during 24 24 So, we can resolve that issue. these cadaver studies, which then led to one of the Page 135 Page 137 1 MR. SNELL: It's okay. Mr. Thornburgh made 1 people observing this, Dan Smith, coming in and 2 his position clear. 2 explained to them the way to do it. 3 BY MR. THORNBURGH: 3 And what Gary Borkes is describing is 4 Q. I'm sorry. Just back to where we were. 4 that design validation is not just a box to check 5 5 What exhibit do you want to discuss with off or, as he describes in the e-mail, a hurdle to 6 the ladies and gentlemen of the jury next? 6 pass, but the way things should be done. 7 7 It's important to get this right so that 8 8 Q. And I'll hand defense counsel a copy of any characteristics of the device that make it 9 that exhibit. 9 unreasonably unsafe or unreasonably less effective 10 What is that exhibit? What is this 10 can be discovered so that those characteristics can 11 document? 11 be changed to make the device more effective and 12 A. It's an e-mail string between Gary 12 more safe. 13 Borkes, who is design quality engineer, and other 13 Q. Okay. So, let me break that down a 14 key Ethicon employees, including Dan Smith, who is 14 little bit because that was a lot of information. 15 an engineer and lead engineer on the TVT-Secur 15 You had indicated that design validation 16 project, Mark Weisberg, Allison London Brown, who 16 is a tool for understanding potential issues with a 17 17 is the worldwide project leader for the TVT-Secur, device or with the IFU? 18 discussing the design validation process. 18 MR. SNELL: Object and leading. 19 Q. Okay. So, let me just try to understand 19 BY MR. THORNBURGH: 20 some things and orient the jury a little bit as 20 Q. What is the purpose of design 21 21 validation? well. 22 What is a -- it says, "Des Val." What 22 A. Well, to validate all of the 23 is design validation? 23 characteristics of the device, which includes the 24 A. It is the process by which a medical 24 device, would include the Instructions for Use, the

35 (Pages 134 to 137)

	Page 138		Page 140
1	technique to implant the device, and the training	1	unreasonably unsafe or if they impact the
2	on how to implant the device.	2	effectiveness of the device.
3	Q. And at this point in time, in 2005, with	3	BY MR. THORNBURGH:
4	respect to the design validation, what was Ethicon	4	Q. Now, I just want to have you orient this
5	attempting to do?	5	for the jury, ladies and gentlemen of the jury.
6	MR. SNELL: Object.	6	If we look at ETH.MESH.05559109 of
7	BY MR. THORNBURGH:	7	Exhibit 1318, there is a discussion that's
8	Q. What, if anything, was Ethicon	8	occurring with Gary Borkes to a number of other
9	attempting to do?	9	Ethicon employees, is that correct?
10	A. Well, this is describing cadaver labs	10	MR. SNELL: Object; leading.
11	that were being done. This is to see how doctors	11	BY THE WITNESS:
12	are able to use the device albeit in a dead body or	12	A. Yes.
13	a cadaver.	13	BY MR. THORNBURGH:
14	Q. And are these is this design	14	Q. And without having to run through all of
15	validation process an important process to the	15	this lengthy sort of these lengthy comments, the
16	ultimate development and launch of products?	16	first bullet point says, "He commented that
17	A. Yes. This helps the design team	17	(somehow) he was shown how to attach the needle
18	discover characteristics of the device that either	18	holder prior to starting the training; and if it
19	make it unreasonably unsafe or make it ineffective.	19	wasn't for that, in his opinion the technique was
20	Q. What, if anything, can happen to	20	not clearly defined via the draft IFU verbiage or
21	patients if design validation protocols aren't	21	the picture."
22	followed?	22	Did I read that correctly?
23	MR. SNELL: Object.	23	MR. SNELL: Object and leading.
24	BY THE WITNESS:	24	BY THE WITNESS:
	Page 139		Page 141
1	Page 139	1	Page 141
1	A. A device that has device characteristics	1 2	A. Yes.
2	A. A device that has device characteristics that make it unreasonably unsafe or make it	2	A. Yes. BY MR. THORNBURGH:
2	A. A device that has device characteristics that make it unreasonably unsafe or make it ineffective in treating the condition that it is	2 3	A. Yes. BY MR. THORNBURGH: Q. And do you have any opinions about that
2 3 4	A. A device that has device characteristics that make it unreasonably unsafe or make it ineffective in treating the condition that it is being used for, if the design validation process is	2 3 4	A. Yes. BY MR. THORNBURGH: Q. And do you have any opinions about that issue, in other words said, in other words
2 3 4 5	A. A device that has device characteristics that make it unreasonably unsafe or make it ineffective in treating the condition that it is being used for, if the design validation process is not done completely, accurately and effectively,	2 3 4 5	A. Yes. BY MR. THORNBURGH: Q. And do you have any opinions about that issue, in other words said, in other words strike that.
2 3 4 5 6	A. A device that has device characteristics that make it unreasonably unsafe or make it ineffective in treating the condition that it is being used for, if the design validation process is not done completely, accurately and effectively, would mean that those characteristics get into a	2 3 4 5 6	A. Yes. BY MR. THORNBURGH: Q. And do you have any opinions about that issue, in other words said, in other words strike that. Do you have any opinions whether or not,
2 3 4 5 6 7	A. A device that has device characteristics that make it unreasonably unsafe or make it ineffective in treating the condition that it is being used for, if the design validation process is not done completely, accurately and effectively, would mean that those characteristics get into a device and women are exposed to the design	2 3 4 5 6 7	A. Yes. BY MR. THORNBURGH: Q. And do you have any opinions about that issue, in other words said, in other words strike that. Do you have any opinions whether or not, with respect to this TVT-Secur design validation,
2 3 4 5 6 7 8	A. A device that has device characteristics that make it unreasonably unsafe or make it ineffective in treating the condition that it is being used for, if the design validation process is not done completely, accurately and effectively, would mean that those characteristics get into a device and women are exposed to the design characteristics that make it unreasonably unsafe or	2 3 4 5 6 7 8	A. Yes. BY MR. THORNBURGH: Q. And do you have any opinions about that issue, in other words said, in other words strike that. Do you have any opinions whether or not, with respect to this TVT-Secur design validation, it would have been appropriate for an Ethicon
2 3 4 5 6 7 8 9	A. A device that has device characteristics that make it unreasonably unsafe or make it ineffective in treating the condition that it is being used for, if the design validation process is not done completely, accurately and effectively, would mean that those characteristics get into a device and women are exposed to the design characteristics that make it unreasonably unsafe or less effective.	2 3 4 5 6 7 8	A. Yes. BY MR. THORNBURGH: Q. And do you have any opinions about that issue, in other words said, in other words strike that. Do you have any opinions whether or not, with respect to this TVT-Secur design validation, it would have been appropriate for an Ethicon employee to show one of the physicians who were
2 3 4 5 6 7 8 9	A. A device that has device characteristics that make it unreasonably unsafe or make it ineffective in treating the condition that it is being used for, if the design validation process is not done completely, accurately and effectively, would mean that those characteristics get into a device and women are exposed to the design characteristics that make it unreasonably unsafe or less effective.  BY MR. THORNBURGH:	2 3 4 5 6 7 8 9	A. Yes. BY MR. THORNBURGH: Q. And do you have any opinions about that issue, in other words said, in other words strike that. Do you have any opinions whether or not, with respect to this TVT-Secur design validation, it would have been appropriate for an Ethicon employee to show one of the physicians who were participating in this design validation how to
2 3 4 5 6 7 8 9 10	A. A device that has device characteristics that make it unreasonably unsafe or make it ineffective in treating the condition that it is being used for, if the design validation process is not done completely, accurately and effectively, would mean that those characteristics get into a device and women are exposed to the design characteristics that make it unreasonably unsafe or less effective.  BY MR. THORNBURGH:  Q. Do you have an opinion whether or not	2 3 4 5 6 7 8	A. Yes. BY MR. THORNBURGH: Q. And do you have any opinions about that issue, in other words said, in other words strike that. Do you have any opinions whether or not, with respect to this TVT-Secur design validation, it would have been appropriate for an Ethicon employee to show one of the physicians who were participating in this design validation how to perform the technique without letting the doctor
2 3 4 5 6 7 8 9 10 11	A. A device that has device characteristics that make it unreasonably unsafe or make it ineffective in treating the condition that it is being used for, if the design validation process is not done completely, accurately and effectively, would mean that those characteristics get into a device and women are exposed to the design characteristics that make it unreasonably unsafe or less effective.  BY MR. THORNBURGH:  Q. Do you have an opinion whether or not companies should take their time in performing	2 3 4 5 6 7 8 9 10	A. Yes. BY MR. THORNBURGH: Q. And do you have any opinions about that issue, in other words said, in other words strike that. Do you have any opinions whether or not, with respect to this TVT-Secur design validation, it would have been appropriate for an Ethicon employee to show one of the physicians who were participating in this design validation how to perform the technique without letting the doctor try to figure out based on his or her review of the
2 3 4 5 6 7 8 9 10 11 12 13	A. A device that has device characteristics that make it unreasonably unsafe or make it ineffective in treating the condition that it is being used for, if the design validation process is not done completely, accurately and effectively, would mean that those characteristics get into a device and women are exposed to the design characteristics that make it unreasonably unsafe or less effective.  BY MR. THORNBURGH:  Q. Do you have an opinion whether or not companies should take their time in performing design validation studies?	2 3 4 5 6 7 8 9 10 11 12 13	A. Yes. BY MR. THORNBURGH: Q. And do you have any opinions about that issue, in other words said, in other words strike that. Do you have any opinions whether or not, with respect to this TVT-Secur design validation, it would have been appropriate for an Ethicon employee to show one of the physicians who were participating in this design validation how to perform the technique without letting the doctor
2 3 4 5 6 7 8 9 10 11	A. A device that has device characteristics that make it unreasonably unsafe or make it ineffective in treating the condition that it is being used for, if the design validation process is not done completely, accurately and effectively, would mean that those characteristics get into a device and women are exposed to the design characteristics that make it unreasonably unsafe or less effective.  BY MR. THORNBURGH:  Q. Do you have an opinion whether or not companies should take their time in performing	2 3 4 5 6 7 8 9 10 11 12	A. Yes. BY MR. THORNBURGH: Q. And do you have any opinions about that issue, in other words said, in other words strike that. Do you have any opinions whether or not, with respect to this TVT-Secur design validation, it would have been appropriate for an Ethicon employee to show one of the physicians who were participating in this design validation how to perform the technique without letting the doctor try to figure out based on his or her review of the IFU how to do the procedure with only using the
2 3 4 5 6 7 8 9 10 11 12 13 14	A. A device that has device characteristics that make it unreasonably unsafe or make it ineffective in treating the condition that it is being used for, if the design validation process is not done completely, accurately and effectively, would mean that those characteristics get into a device and women are exposed to the design characteristics that make it unreasonably unsafe or less effective.  BY MR. THORNBURGH:  Q. Do you have an opinion whether or not companies should take their time in performing design validation studies?  MR. SNELL: Object.	2 3 4 5 6 7 8 9 10 11 12 13 14	A. Yes. BY MR. THORNBURGH: Q. And do you have any opinions about that issue, in other words said, in other words strike that. Do you have any opinions whether or not, with respect to this TVT-Secur design validation, it would have been appropriate for an Ethicon employee to show one of the physicians who were participating in this design validation how to perform the technique without letting the doctor try to figure out based on his or her review of the IFU how to do the procedure with only using the IFU?
2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. A device that has device characteristics that make it unreasonably unsafe or make it ineffective in treating the condition that it is being used for, if the design validation process is not done completely, accurately and effectively, would mean that those characteristics get into a device and women are exposed to the design characteristics that make it unreasonably unsafe or less effective.  BY MR. THORNBURGH:  Q. Do you have an opinion whether or not companies should take their time in performing design validation studies?  MR. SNELL: Object. BY THE WITNESS:  A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14	A. Yes. BY MR. THORNBURGH: Q. And do you have any opinions about that issue, in other words said, in other words strike that. Do you have any opinions whether or not, with respect to this TVT-Secur design validation, it would have been appropriate for an Ethicon employee to show one of the physicians who were participating in this design validation how to perform the technique without letting the doctor try to figure out based on his or her review of the IFU how to do the procedure with only using the IFU? MR. SNELL: Object.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. A device that has device characteristics that make it unreasonably unsafe or make it ineffective in treating the condition that it is being used for, if the design validation process is not done completely, accurately and effectively, would mean that those characteristics get into a device and women are exposed to the design characteristics that make it unreasonably unsafe or less effective.  BY MR. THORNBURGH:  Q. Do you have an opinion whether or not companies should take their time in performing design validation studies?  MR. SNELL: Object. BY THE WITNESS:  A. Yes. BY MR. THORNBURGH:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. Yes. BY MR. THORNBURGH:  Q. And do you have any opinions about that issue, in other words said, in other words strike that.  Do you have any opinions whether or not, with respect to this TVT-Secur design validation, it would have been appropriate for an Ethicon employee to show one of the physicians who were participating in this design validation how to perform the technique without letting the doctor try to figure out based on his or her review of the IFU how to do the procedure with only using the IFU?  MR. SNELL: Object. BY THE WITNESS:
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. A device that has device characteristics that make it unreasonably unsafe or make it ineffective in treating the condition that it is being used for, if the design validation process is not done completely, accurately and effectively, would mean that those characteristics get into a device and women are exposed to the design characteristics that make it unreasonably unsafe or less effective.  BY MR. THORNBURGH:  Q. Do you have an opinion whether or not companies should take their time in performing design validation studies?  MR. SNELL: Object. BY THE WITNESS:  A. Yes. BY MR. THORNBURGH: Q. What's that opinion?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Yes. BY MR. THORNBURGH: Q. And do you have any opinions about that issue, in other words said, in other words strike that. Do you have any opinions whether or not, with respect to this TVT-Secur design validation, it would have been appropriate for an Ethicon employee to show one of the physicians who were participating in this design validation how to perform the technique without letting the doctor try to figure out based on his or her review of the IFU how to do the procedure with only using the IFU? MR. SNELL: Object. BY THE WITNESS: A. I do have an opinion. BY MR. THORNBURGH:
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. A device that has device characteristics that make it unreasonably unsafe or make it ineffective in treating the condition that it is being used for, if the design validation process is not done completely, accurately and effectively, would mean that those characteristics get into a device and women are exposed to the design characteristics that make it unreasonably unsafe or less effective.  BY MR. THORNBURGH:  Q. Do you have an opinion whether or not companies should take their time in performing design validation studies?  MR. SNELL: Object. BY THE WITNESS:  A. Yes. BY MR. THORNBURGH:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Yes. BY MR. THORNBURGH: Q. And do you have any opinions about that issue, in other words said, in other words strike that. Do you have any opinions whether or not, with respect to this TVT-Secur design validation, it would have been appropriate for an Ethicon employee to show one of the physicians who were participating in this design validation how to perform the technique without letting the doctor try to figure out based on his or her review of the IFU how to do the procedure with only using the IFU? MR. SNELL: Object. BY THE WITNESS: A. I do have an opinion. BY MR. THORNBURGH: Q. And what's that?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. A device that has device characteristics that make it unreasonably unsafe or make it ineffective in treating the condition that it is being used for, if the design validation process is not done completely, accurately and effectively, would mean that those characteristics get into a device and women are exposed to the design characteristics that make it unreasonably unsafe or less effective.  BY MR. THORNBURGH:  Q. Do you have an opinion whether or not companies should take their time in performing design validation studies?  MR. SNELL: Object. BY THE WITNESS:  A. Yes. BY MR. THORNBURGH: Q. What's that opinion? MR. SNELL: Same objection. BY THE WITNESS:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Yes. BY MR. THORNBURGH:  Q. And do you have any opinions about that issue, in other words said, in other words strike that.  Do you have any opinions whether or not, with respect to this TVT-Secur design validation, it would have been appropriate for an Ethicon employee to show one of the physicians who were participating in this design validation how to perform the technique without letting the doctor try to figure out based on his or her review of the IFU how to do the procedure with only using the IFU?  MR. SNELL: Object. BY THE WITNESS:  A. I do have an opinion. BY MR. THORNBURGH: Q. And what's that? A. That would not be appropriate.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. A device that has device characteristics that make it unreasonably unsafe or make it ineffective in treating the condition that it is being used for, if the design validation process is not done completely, accurately and effectively, would mean that those characteristics get into a device and women are exposed to the design characteristics that make it unreasonably unsafe or less effective.  BY MR. THORNBURGH:  Q. Do you have an opinion whether or not companies should take their time in performing design validation studies?  MR. SNELL: Object. BY THE WITNESS:  A. Yes. BY MR. THORNBURGH: Q. What's that opinion?  MR. SNELL: Same objection. BY THE WITNESS: A. That they should take their time and	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. Yes. BY MR. THORNBURGH:  Q. And do you have any opinions about that issue, in other words said, in other words strike that.  Do you have any opinions whether or not, with respect to this TVT-Secur design validation, it would have been appropriate for an Ethicon employee to show one of the physicians who were participating in this design validation how to perform the technique without letting the doctor try to figure out based on his or her review of the IFU how to do the procedure with only using the IFU?  MR. SNELL: Object. BY THE WITNESS:  A. I do have an opinion. BY MR. THORNBURGH: Q. And what's that? A. That would not be appropriate.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. A device that has device characteristics that make it unreasonably unsafe or make it ineffective in treating the condition that it is being used for, if the design validation process is not done completely, accurately and effectively, would mean that those characteristics get into a device and women are exposed to the design characteristics that make it unreasonably unsafe or less effective.  BY MR. THORNBURGH:  Q. Do you have an opinion whether or not companies should take their time in performing design validation studies?  MR. SNELL: Object. BY THE WITNESS:  A. Yes. BY MR. THORNBURGH: Q. What's that opinion? MR. SNELL: Same objection. BY THE WITNESS:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. BY MR. THORNBURGH:  Q. And do you have any opinions about that issue, in other words said, in other words strike that.  Do you have any opinions whether or not, with respect to this TVT-Secur design validation, it would have been appropriate for an Ethicon employee to show one of the physicians who were participating in this design validation how to perform the technique without letting the doctor try to figure out based on his or her review of the IFU how to do the procedure with only using the IFU?  MR. SNELL: Object. BY THE WITNESS:  A. I do have an opinion. BY MR. THORNBURGH: Q. And what's that? A. That would not be appropriate. Q. And why is that?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. A device that has device characteristics that make it unreasonably unsafe or make it ineffective in treating the condition that it is being used for, if the design validation process is not done completely, accurately and effectively, would mean that those characteristics get into a device and women are exposed to the design characteristics that make it unreasonably unsafe or less effective.  BY MR. THORNBURGH:  Q. Do you have an opinion whether or not companies should take their time in performing design validation studies?  MR. SNELL: Object.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:  Q. What's that opinion?  MR. SNELL: Same objection.  BY THE WITNESS:  A. That they should take their time and know both clinically test and test in the design	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. BY MR. THORNBURGH: Q. And do you have any opinions about that issue, in other words said, in other words strike that. Do you have any opinions whether or not, with respect to this TVT-Secur design validation, it would have been appropriate for an Ethicon employee to show one of the physicians who were participating in this design validation how to perform the technique without letting the doctor try to figure out based on his or her review of the IFU how to do the procedure with only using the IFU? MR. SNELL: Object. BY THE WITNESS: A. I do have an opinion. BY MR. THORNBURGH: Q. And what's that? A. That would not be appropriate. Q. And why is that? A. Because the Instructions for Use is the

	Page 142		Page 144
1	the device, which is at the time that the device is	1	but I am through making non-value added changes to
2	being placed. The Instructions for Use should be	2	a document that is 1,000 times more accurate and
3	able to describe how a device is implanted.	3	complete than TVT."
4	If this doctor, who is described in this	4	Did I read that correctly?
5	e-mail, could not clearly if the technique could	5	A. Yes.
6	not be clearly defined via the draft of the IFU	6	MR. SNELL: Objection and leading.
7	verbiage, then that shows that the IFU verbiage has	7	BY MR. THORNBURGH:
8	characteristics of it that make it unreasonably	8	Q. Dan Smith goes on and says or writes, "I
9	unsafe or defective.	9	have drawn the line, unless someone can demonstrate
10	Q. In this first bullet point what was	10	a 'real' deficiency in the document. This is a
11	being recommended?	11	waste of time and it is holding up the project in
12	A. That there might be or there would be	12	many ways."
13	benefit for making the steps that are described in	13	Did I read that correctly?
14	the procedural steps more clear and accurate so	14	MR. SNELL: Object and leading.
15	that a doctor would be able to use the Instructions	15	BY THE WITNESS:
16	for Use in a safe and effective way to implant the	16	A. Yes.
17	device in women.	17	BY MR. THORNBURGH:
18	Q. Okay. And does Dan Smith respond to the	18	Q. And is it appropriate for Dan Smith, the
19	comments that Gary Borkes shared?	19	inventor or co-inventor of the TVT-Secur device,
20	A. Yes.	20	who is a non-doctor, to be pushing back on whether
21	Q. And what was Dan Smith's response?	21	or not the IFU should be changed to make it more
22	MR. SNELL: Object.	22	accurate so that physicians can safely implant the
23	BY THE WITNESS:	23	TVT-Secur device?
24	A. Basically he states that "I am through	24	MR. SNELL: Object.
	Page 143		Page 145
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1	making non-value added changes to a document," and	1	BY THE WITNESS:
1 2	making non-value added changes to a document," and that document is the Instructions for Use.	1 2	
			BY THE WITNESS:  A. Yes, I have an opinion. BY MR. THORNBURGH:
2	that document is the Instructions for Use.	2	A. Yes, I have an opinion.
2	that document is the Instructions for Use. BY MR. THORNBURGH:	2 3	A. Yes, I have an opinion. BY MR. THORNBURGH:
2 3 4	that document is the Instructions for Use. BY MR. THORNBURGH: Q. Dan Smith a doctor or not doctor?	2 3 4	<ul><li>A. Yes, I have an opinion.</li><li>BY MR. THORNBURGH:</li><li>Q. What's that opinion?</li></ul>
2 3 4 5	that document is the Instructions for Use. BY MR. THORNBURGH: Q. Dan Smith a doctor or not doctor? MR. SNELL: Objection.	2 3 4 5	<ul><li>A. Yes, I have an opinion.</li><li>BY MR. THORNBURGH:</li><li>Q. What's that opinion?</li><li>A. No, it is not appropriate.</li></ul>
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37 (Pages 142 to 145)

	Page 146		Page 148
1	BY THE WITNESS:	1	Q. What's that opinion?
2	A. Yes.	2	A. They did not.
3	BY MR. THORNBURGH:	3	Q. And do you have an opinion whether or
4	Q. Do you agree with Gary Borkes?	4	not Ethicon's failure to properly perform the
5	A. Yes.	5	TVT-Secur design validation ended up as, using Gary
6	Q. He writes, goes on and writes towards	6	Borkes' words, biting the product down the road?
7	the end of this second paragraph, "I believe the	7	MR. SNELL: Object and leading.
8	timeline pressures are recognized and felt by	8	BY THE WITNESS:
9	everyone - believe me, Dan, the overwhelming load	9	A. I do have an opinion.
10	(even me - how about that). But we also have to	10	BY MR. THORNBURGH:
11	properly evaluate user input, or it could bite the	11	Q. And what's that?
12	product down the road."	12	MR. SNELL: Same.
13	Did I read that correctly?	13	BY THE WITNESS:
14	MR. SNELL: Object and leading.	14	A. That that is a correct statement by Gary
15	BY THE WITNESS:	15	Borkes.
16	A. You missed one line that says, "Everyone	16	BY MR. THORNBURGH:
17	I talk to says how under the gun they are and how	17	Q. And we will get into this in more
18	much they are trying to push to support you and the	18	more detail later on.
19	project despite the overwhelming load."	19	But do you have an opinion whether or
20	But beside that, yes, you read that	20	not the TVT-Secur ultimately was a failed product?
21	correctly.	21	A. Yes, I do have an opinion.
22	BY MR. THORNBURGH:	22	Q. And what's that opinion?
23	Q. And do you have any opinions about this	23	A. That it was a failed product.
24	response by Gary Borkes?	24	Q. And what's the basis for that opinion?
			Page 149
1	MR. SNELL: Object.		
_		1	Δ Internal Ethicon documents, particularly
2	•	1 2	A. Internal Ethicon documents, particularly
2	BY THE WITNESS:	2	a document from Dan Smith, the inventor.
3	BY THE WITNESS:  A. Yes, I do have an opinion.	2 3	a document from Dan Smith, the inventor.  Q. And ultimately did let me ask this
3 4	BY THE WITNESS:  A. Yes, I do have an opinion. BY MR. THORNBURGH:	2 3 4	a document from Dan Smith, the inventor.  Q. And ultimately did let me ask this question: Is the TVT-Secur still on the market?
3	BY THE WITNESS:  A. Yes, I do have an opinion. BY MR. THORNBURGH: Q. What's the opinion?	2 3	a document from Dan Smith, the inventor.  Q. And ultimately did let me ask this question: Is the TVT-Secur still on the market?  A. No, it is not.
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	BY THE WITNESS:  A. Yes, I do have an opinion. BY MR. THORNBURGH: Q. What's the opinion? MR. SNELL: Same. BY THE WITNESS: A. That if the design validation process is not done in the appropriate manner, then characteristics of the device that make it unreasonably unsafe or make it unreasonably less effective will not be identified prior to the launch of the product and that women will be exposed to a device that has design characteristics that make it unreasonably unsafe or unreasonably uneffective. BY MR. THORNBURGH: Q. Do you have an opinion whether or not	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	a document from Dan Smith, the inventor.  Q. And ultimately did let me ask this question: Is the TVT-Secur still on the market?  A. No, it is not.  Q. And do you have an understanding as to why?  A. It was removed from the market in 2012.  Q. And do you have an understanding as to whether or not the safety or efficacy of the TVT-Secur product led to that determination?  MR. SNELL: Object.  BY MR. THORNBURGH:  Q. Do you have an opinion based on your review of the internal documents and the medical literature?  MR. SNELL: Object.  BY THE WITNESS:
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	BY THE WITNESS:  A. Yes, I do have an opinion. BY MR. THORNBURGH: Q. What's the opinion? MR. SNELL: Same. BY THE WITNESS: A. That if the design validation process is not done in the appropriate manner, then characteristics of the device that make it unreasonably unsafe or make it unreasonably less effective will not be identified prior to the launch of the product and that women will be exposed to a device that has design characteristics that make it unreasonably unsafe or unreasonably uneffective. BY MR. THORNBURGH: Q. Do you have an opinion whether or not Ethicon properly performed its design validation of the TVT-Secur device?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	a document from Dan Smith, the inventor.  Q. And ultimately did let me ask this question: Is the TVT-Secur still on the market?  A. No, it is not.  Q. And do you have an understanding as to why?  A. It was removed from the market in 2012.  Q. And do you have an understanding as to whether or not the safety or efficacy of the TVT-Secur product led to that determination?  MR. SNELL: Object.  BY MR. THORNBURGH:  Q. Do you have an opinion based on your review of the internal documents and the medical literature?  MR. SNELL: Object.  BY THE WITNESS:  A. Yes, I do.  BY MR. THORNBURGH:
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY THE WITNESS:  A. Yes, I do have an opinion. BY MR. THORNBURGH: Q. What's the opinion? MR. SNELL: Same. BY THE WITNESS: A. That if the design validation process is not done in the appropriate manner, then characteristics of the device that make it unreasonably unsafe or make it unreasonably less effective will not be identified prior to the launch of the product and that women will be exposed to a device that has design characteristics that make it unreasonably unsafe or unreasonably uneffective. BY MR. THORNBURGH: Q. Do you have an opinion whether or not Ethicon properly performed its design validation of the TVT-Secur device? MR. SNELL: Object.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	a document from Dan Smith, the inventor.  Q. And ultimately did let me ask this question: Is the TVT-Secur still on the market?  A. No, it is not.  Q. And do you have an understanding as to why?  A. It was removed from the market in 2012.  Q. And do you have an understanding as to whether or not the safety or efficacy of the TVT-Secur product led to that determination?  MR. SNELL: Object.  BY MR. THORNBURGH:  Q. Do you have an opinion based on your review of the internal documents and the medical literature?  MR. SNELL: Object.  BY THE WITNESS:  A. Yes, I do.  BY MR. THORNBURGH:  Q. What's that opinion? What's that
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY THE WITNESS:  A. Yes, I do have an opinion. BY MR. THORNBURGH: Q. What's the opinion? MR. SNELL: Same. BY THE WITNESS: A. That if the design validation process is not done in the appropriate manner, then characteristics of the device that make it unreasonably unsafe or make it unreasonably less effective will not be identified prior to the launch of the product and that women will be exposed to a device that has design characteristics that make it unreasonably unsafe or unreasonably uneffective. BY MR. THORNBURGH: Q. Do you have an opinion whether or not Ethicon properly performed its design validation of the TVT-Secur device? MR. SNELL: Object. BY THE WITNESS:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	a document from Dan Smith, the inventor.  Q. And ultimately did let me ask this question: Is the TVT-Secur still on the market?  A. No, it is not.  Q. And do you have an understanding as to why?  A. It was removed from the market in 2012.  Q. And do you have an understanding as to whether or not the safety or efficacy of the TVT-Secur product led to that determination?  MR. SNELL: Object.  BY MR. THORNBURGH:  Q. Do you have an opinion based on your review of the internal documents and the medical literature?  MR. SNELL: Object.  BY THE WITNESS:  A. Yes, I do.  BY MR. THORNBURGH:  Q. What's that opinion? What's that opinion?

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	Page 150		Page 152
1	removed was one of the issues that led to it	1	A. Dr. Weisberg is a Senior Medical
2	being removed from the market.	2	Director at Ethicon.
3	MR. THORNBURGH: Okay. Let's go ahead and	3	Q. And what is the title of this document?
4	take a break.	4	A. It's the Clinical Expert Report for the
5	THE VIDEOGRAPHER: Okay. The time is 12 noon	5	TVT-Secur.
6	and we're going off the video record.	6	Q. And you testified just a moment ago this
7	(WHEREUPON, the following	7	was dated December 2, 2005?
8	proceedings were had off the video	8	A. Correct.
9	record:)	9	Q. And when was the TVT-Secur product
10	MR. SNELL: Before we go off the steno record,	10	launched?
11	I would note we have been unable to locate P1318 on	11	A. September
12	the reliance list. I move to strike any and all	12	MR. SNELL: Object.
13	testimony regarding P1318.	13	BY THE WITNESS:
14	MR. THORNBURGH: I will show you now or I will	14	A. September 20, 2006.
15	show you later. We can deal with it.	15	BY MR. THORNBURGH:
16	MR. SNELL: I'm just saying Paul has checked	16	Q. Okay. And was this document signed a
17	and checked and checked. He doesn't have Borkes'	17	little less than a year prior to the launch of the
18	depo. He doesn't have this document on his	18	TVT-Secur product?
19	reliance list.	19	A. Yes.
20	MR. THORNBURGH: I don't want to show him	20	Q. And you've testified previously about
21	Borkes' deposition. Borkes wasn't deposed.	21	randomized controlled trials and what they are. Is
22	MR. SNELL: It's not on his reliance list as	22	that correct?
23	far as I can tell.	23	A. Yes.
24	MR. BRADFORD: He's making an objection.	24	Q. And I don't want to go into great
	Page 151		Page 153
1	MR. SNELL: I'm just making an objection. No	1	detail, but what is a randomized controlled trial?
2	big deal.	2	A. Randomized controlled trials are high
3	MR. THORNBURGH: That's fine.	3	level evidence, some of the highest level of
4	MR. SNELL: If I'm wrong, I'm wrong. I will	4	evidence in a single clinical study where a
5	freely say I'm wrong. But we checked and checked.	5	hypothesis is generated, a method of looking at
6	I asked Paul to check four different ways.	6	that hypothesis is created, and patients are put in
7	THE WITNESS: I will be a witness. Burt has	7	either one group getting treatment or another
8	said, "I was wrong."	8	group, which is called the control group.
9	MR. SNELL: Yes, I will freely admit when I am	9	They're randomly assigned, which should
10	totally wrong.	10	make the groups equal in their similarity as far as
11	(WHEREUPON, a recess was had	11	medical conditions, age, and the like, and then the
12	from 12:00 to 1:07 p.m.)	12	data is collected and analyzed.
13	THE VIDEOGRAPHER: The time is 1:07 p.m. and	13	Q. Did Ethicon do you know whether or
	we're back on the video record.	14	not Ethicon had conducted a randomized controlled
14 15		15	trial prior to launching or selling to battents or
14	BY MR. THORNBURGH:	15 16	trial prior to launching or selling to patients or doctors the TVT-Secur device?
14 15 16	BY MR. THORNBURGH: Q. Good afternoon, Doctor.		doctors the TVT-Secur device?
14 15 16 17	BY MR. THORNBURGH: Q. Good afternoon, Doctor. A. Good afternoon.	16	
14 15 16 17 18	BY MR. THORNBURGH: Q. Good afternoon, Doctor. A. Good afternoon. Q. Dr. Rosenzweig, what's the next exhibit	16 17	doctors the TVT-Secur device?  MR. SNELL: Object. BY THE WITNESS:
14 15 16 17 18	BY MR. THORNBURGH: Q. Good afternoon, Doctor. A. Good afternoon. Q. Dr. Rosenzweig, what's the next exhibit in your binder, which is I think we've marked as	16 17 18 19	doctors the TVT-Secur device?  MR. SNELL: Object. BY THE WITNESS:  A. They did not.
14 15 16 17 18 19 20	BY MR. THORNBURGH: Q. Good afternoon, Doctor. A. Good afternoon. Q. Dr. Rosenzweig, what's the next exhibit in your binder, which is I think we've marked as Exhibit No. 5, that you'd like to discuss?	16 17 18	doctors the TVT-Secur device?  MR. SNELL: Object.  BY THE WITNESS:  A. They did not.  BY MR. THORNBURGH:
14 15 16 17 18 19 20 21	BY MR. THORNBURGH: Q. Good afternoon, Doctor. A. Good afternoon. Q. Dr. Rosenzweig, what's the next exhibit in your binder, which is I think we've marked as Exhibit No. 5, that you'd like to discuss? A. P number 1177. It's the Clinical Expert	16 17 18 19 20 21	doctors the TVT-Secur device?  MR. SNELL: Object. BY THE WITNESS:  A. They did not. BY MR. THORNBURGH: Q. Let me ask that a better way since I got
14 15 16 17 18 19 20 21	BY MR. THORNBURGH: Q. Good afternoon, Doctor. A. Good afternoon. Q. Dr. Rosenzweig, what's the next exhibit in your binder, which is I think we've marked as Exhibit No. 5, that you'd like to discuss? A. P number 1177. It's the Clinical Expert Report for the TVT-Secur device authored by	16 17 18 19 20	doctors the TVT-Secur device?  MR. SNELL: Object. BY THE WITNESS:  A. They did not. BY MR. THORNBURGH:  Q. Let me ask that a better way since I got an objection.
14 15 16 17 18 19 20 21	BY MR. THORNBURGH: Q. Good afternoon, Doctor. A. Good afternoon. Q. Dr. Rosenzweig, what's the next exhibit in your binder, which is I think we've marked as Exhibit No. 5, that you'd like to discuss? A. P number 1177. It's the Clinical Expert	16 17 18 19 20 21 22	doctors the TVT-Secur device?  MR. SNELL: Object. BY THE WITNESS:  A. They did not. BY MR. THORNBURGH: Q. Let me ask that a better way since I got

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launching the TVT-Secur product?   2		Page 154		Page 156
2 A. They did not. 3 Q. Do you know whether or not Ethicon had 4 initially planned on conducting a randomized 5 controlled trial before launching the TVT-Secur? 6 MR. SNELL: Object. 7 BY THE WITNESS: 8 A. Yes, I saw documents that discussed 9 conducting a randomized controlled trial. 10 BY MR. THORNBURGH: 11 Q. And do you have an understanding as to 12 the reason why Ethicon chose not to conduct a 13 randomized controlled trial prior to launching the 14 product? 15 MR. SNELL: Object. 16 BY THE WITNESS: 16 BY THE WITNESS: 17 A. Yes. 18 BY MR. THORNBURGH: 19 Q. And what's that understanding? 20 A. Due to budget constraints. 21 Q. And what's that understanding? 22 A. Due to budget constraints. 23 A. Internal Ethicon documents. 24 Q. And ultimately did Ethicon conduct any 25 study in humans before they launched the TVT-Secur product? 26 A. There was a study that was started, if I recall, in April of 2006 and prior to launch they 27 bad data, five-week data on 31 patients. 28 C. Q. Okay. And, so, this document, dated 29 C. December 2, 2005, was signed prior to the beginning of the clinical study that was done by Ethicon? 29 A. Yes, based on my understanding, and the duration of the available data at launch? 3 A. Nes. 3 C. Well, as of December 2, 2005, or Weisberg and efficativeness are studies to support the safety and efficitiveness are on to recessary to post one stewerd centers and they had the safety and efficacy of the TVT-Secur product? 3 A. Internal Ethicon documents. 4 Q. Did Dr. Weisberg, the Medical Dr. Weisberg and efficacy of the product prior to release. 4 Dr. Weisberg sign off on the safety and efficacy of the product prior to release. 5 Dr. Weisberg sign off on the safety and efficacy of the product prior to release. 6 Q. Okay. And the clinical study that was done by Ethicon? 7 Dr. Weisberg sign off on the safety and efficacy of the PVT-Secur product before the clinical study that was done by Ethicon? 8 Dr. Weisberg sign off on the safety and efficacy of the PVT-Secur product before the clinical study	1	launching the TVT-Secur product?	1	No. from P1177 ending in 243, and just let me know
3   Q. Do you know whether or not Ethicon had initially planned on conducting a randomized controlled trial before launching the TVT-Secur?	2		2	
4 Q. What's the significance, if any, of this page from Exhibit P1177? 6 MR. SNELL: Object. 7 BY THE WITNESS: 8 A. Yes, I saw documents that discussed conducting a randomized controlled trial. 10 BY MR. THORNBURGH: 11 Q. And do you have an understanding as to the reason why Ethicon chose not to conduct a randomized controlled trial prior to launching the product? 15 MR. SNELL: Object. 16 BY THE WITNESS: 17 A. Yes. 18 MR. STHLU Object. 19 WITHE WITNESS: 17 A. Yes. 18 BY MR. THORNBURGH: 19 Q. And what's that understanding? 20 A. Due to budget constraints. 21 Q. And what's the basis for that opinion, and that testimony? 22 that testimony? 23 A. Internal Ethicon documents. 24 Q. And ultimately did Ethicon conduct any product? 25 product? 26 A. There was a study that was started, if I received in April of 2006 and prior to launch they had data, five-week data on 31 patients. 26 Q. Okay. And, so, this document, dated December 2, 2005, was signed prior to the beginning of the clinical study that was done by Ethicon? 27 A. Wesherg concluded what was the more and the duration of the available data at launch? 28 A. Yes. 29 Q. Okay. And, so, this document, dated December 2, 2005, and was first human stated what was stored the the TVT-Secur product? 29 A. Yes, based on my understanding. 30 Q. Okay. And, so, this document, dated December 2, 2005, was signed prior to be beginning of the clinical study that was done by Ethicon? 31 A. There was a study that was done by Ethicon? 4 A. Well, is the significance, if any, of this page from Exhibit P1177? 4 A. Well, and discussed on the page of the decument steply out opinions. The page of the deficient study that was done at several centers and they had data on 31 patients was a formal page of the deficient study that was done at several centers and they had data on 31 patients was an ordinal page of the deficient study that was how many patients and the duration of the available data at launch? 4 A. Well, it was a prospective study that was done at several centers and they had dat	3	•	3	-
5   Controlled trial before launching the TVT-Secur?   6   MR. SNELL: Object.   7   BY THE WITNESS:   7   Dr. Weisberg bad signed off on the safety and effectiveness are not necessary prior to releasing the product.   2   Dr. Weisberg bad signed off on the safety and effectiveness are not necessary prior to releasing the product.   2   Dr. Weisberg had signed off on the safety and efficiency of the TVT-Secur product prior to launching the product?   14   Dr. Weisberg had signed off on the safety and efficiency of the TVT-Secur product prior to launching the product?   14   Dr. Weisberg had signed off on the safety and efficiency of the TVT-Secur product prior to launching the product?   14   Dr. Weisberg had signed off on the safety and efficiency of the TVT-Secur product prior to launching the product?   14   Dr. Weisberg had signed off on the safety and efficiency of the TVT-Secur product?   15   A. Yes.   Dr. Weisberg had signed off on the safety and efficiency of the TVT-Secur product?   16   Dr. Weisberg had signed off on the safety and efficiency of the TVT-Secur product?   16   Dr. Weisberg had signed off on the safety and efficiency of the TVT-Secur product?   16   Dr. Weisberg had signed off on the safety and efficiency of the TVT-Secur product?   16   Dr. Weisberg had signed off on the safety and efficiency of the TVT-Secur product?   17   Dr. Weisberg had signed off on the safety and efficiency of the TVT-Secur product?   18   Dr. Weisberg had signed off on the safety and efficiency of the product prior to launch they be prior			4	
6 MR, SNELL: Object. 7 BY THE WITNESS: 8 A. Yes, I saw documents that discussed conducting a randomized controlled trial. 10 BY MR. THORNBURGH: 11 Q. And do you have an understanding as to the reason why Ethicon chose not to conduct a randomized controlled trial prior to launching the product? 15 MR, SNELL: Object. 16 BY THE WITNESS: 16 BY THE WITNESS: 17 A. Yes. 18 BY MR. THORNBURGH: 19 Q. And what's that understanding? 10 Q. And what's that understanding? 10 Q. And what's that bunderstanding? 11 Q. And what's that bunderstanding? 12 Q. And what's that bunderstanding? 13 A. Internal Ethicon documents. 14 Q. And what's that bunderstanding? 15 Study in humans before they launched the TVT-Secur product? 16 Page 155 1 study in humans before they launched the TVT-Secur product? 2 product? 2 product? 3 A. There was a study that was started, if I recall, in April of 2006 and prior to launch they had data, five-week data on 31 patients. 4 Q. Okay. And, so, this document, dated December 2, 2005, br. Weisberg had adiate, five-week data on 31 patients. 4 Q. Okay. And the clinical study that was 10 document of the available data at launch? 4 A. Well, it was a prospective study that was 10 document of the available data at launch? 4 A. Well, it was a prospective study that was 10 patients was done at several centers and they had data on 31 patients was done at several centers and they had data on 31 patients was done at several centers and they had data on 31 patients was done at several centers and they had data on 31 patients was done at several centers and they had data on 31 patients was done at several centers and they had data on 31 patients was done at several centers and they had data on 31 patients was done at several centers and they had data on 31 patients was done at several centers and they had data on 31 patients was done at several centers and they had data on 31 patients was done at several centers and they had data on 31 patients was done at several centers and they had data on 31 patients was done at seve			5	
Page 155   Study in humans before they launched the TVT-Secur product?   A. There was a study that was started, if I recall, in April of 2006 and prior to launch they had data, five-week data on 31 patients.   A. Yes, saw done at several centers and they had data on 31 patients that had been treated with the TVT-Secur product?   A. Yes, saw done at several centers and they had data on 31 patients that had been treated with the TVT-Secur product?   A. Yes, saw done at several centers and they had data on 31 patients that had been treated with the TVT-Secur and the duration of the available data at launch?   A. Yes, saw done at several centers and they had data on 31 patients that had been treated with the TVT-Secur and the duration of Dr. Martin Weisberg for your opinions?   A. Yes, saw done vestimony of Dr. Martin Weisberg for your opinions?   A. Yes, saw done to to conduct and study or the safety and efficacy of the TVT-Secur product;   A. Yes, saw done by Ethicon conduct any   Dr. Weisberg pad signed off on the safety and efficacy of the TVT-Secur photouct product;   A. Yes, saw document support your opinions with respect to the clinical control studies or the First Human Use Study that was done by Ethicon product;   By Mr. THORNBURGH:   By Ethicon in April, began in April of 2006?   Mr. SNFLL: Object.   By Mr. THORNBURGH:   Dr. Weisberg thad single of the document support your opinions?   A. A. There was a study that was started, if I   A. Yes, saw done by Ethicon?   A. Yes, saw done by Et				~ ~
8 A. Yes, I saw documents that discussed 9 conducting a randomized controlled trial. 10 BY MR, THORNBURGH: 11 Q. And do you have an understanding as to 12 the reason why Ethicon chose not to conduct a 13 randomized controlled trial prior to launching the 14 product? 15 MR, SNELL: Object. 16 BY THE WITNESS: 17 A. Yes. 18 BY MR, THORNBURGH: 19 Q. And what's that understanding? 20 A. Due to budget constraints. 21 Q. And what's the basis for that opinion, 22 that testimony? 23 A. Internal Ethicon documents. 24 Q. And ultimately did Ethicon conduct any 25 Page 155 26 Q. Okay. And, so, this document, dated 27 December 2, 2005, was signed prior to launch they 28 had data, five-week data on 31 patients that had been treated with the TVT-Secur 29 of the clinical study that was one as reveral centers and they had data on 31 21 done prior to launch, any on justs briefly describe 22 what kind of study that was, how many patients and 23 the duration of the available data at launch? 24 A. Well, it was a prospective study that 25 was done at several centers and they had data on 31 26 patients that had been treated with the TVT-Secur 27 and had the TVT-Secur in them for five weeks. 28 Q. A. A Well, it was a prospective study that 29 A. Well, it was a prospective study that 30 A. Well, it was a prospective study that 31 Wessers are not necessary to determine safety and efficacy of the product prior to release. 32 Q. And what's that been treated with the TVT-Secur and had the TVT-Secur in them for five weeks. 34 Q. Okay. And did you also read the 35 testimony of Dr. Martin Weisberg for your opinions? 36 the direction of the add at an on 31 patients that had been treated with the TVT-Secur and had the TVT-Secur in them for five weeks. 36 Q. Okay. And did you rely at least in part on the 37 testimony of Dr. Martin Weisberg for your opinions? 38 A. Yes. 39 A. Yes. 30 A. Tree was a study that was done be given by the first human use Study oncluded that additional clinical studies were not necessary to determine safety and efficacy o		-		
9 conducting a randomized controlled trial. 10 BY MR. THORNBURGH: 11 Q. And do you have an understanding as to the reason why Ethicon chose not to conduct a randomized controlled trial prior to launching the product? 13 randomized controlled trial prior to launching the product? 14 product? 15 MR. SNELL: Object. 16 BY THE WITNESS: 16 BY MR. THORNBURGH: 17 A. Yes. 18 BY MR. THORNBURGH: 19 Q. And what's that understanding? 20 A. Due to budget constraints. 21 Q. And what's the basis for that opinion, that testimony? 22 A. Internal Ethicon documents. 23 A. Internal Ethicon documents. 24 Q. And ultimately did Ethicon conduct any 25 product? 26 A. There was a study that was stared, if I recall, in April of 2006 and prior to launch they and data, five-week data on 31 patients. 26 Q. Okay. And, so, this document, dated the duration of the available data at launch? 27 A. Yes. 28 A. Yes. 29 A. Yes, based on my understanding. 30 G. Do, Van, And the clinical study that was done as several centers and they had data on 31 patients that had been reated with the TVT-Secur and had the TVT-Secur in them for five weeks. 31 Q. Okay. And did you also read the testimony of Dr. Martin Weisberg? 32 A. Yes. 33 A. Yes with the duration of the available data at launch? 44 Page 155 45 Page 155 46 Page 155 57 Of the document support your opinions? 58 A. As of December 2, 2005, Dr. Weisberg had already concluded -Dr. Weisberg, the Medical Director at Ethicon, had already concluded that additional clinical study that was done or be ressary to to release. 40 Do you agree with that determination by Dr. Weisberg? 41 A. Wes. 41 Page 157 42 Page 157 43 A. There was a study that was done or by Ethicon in April of 2006 and prior to launch? 44 Page 155 58 Page 157 59 Of the document support your opinions? 50 Of the clinical study that was done or by Ethicon in April of 2006 and prior to launching that the duration of the value of the				
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15 was done at several centers and they had data on 31 16 patients that had been treated with the TVT-Secur 17 and had the TVT-Secur in them for five weeks. 18 Q. Okay. And did you also read the 19 testimony of Dr. Martin Weisberg? 20 A. Yes. 21 Q. And did you rely at least in part on the 22 testimony of Dr. Martin Weisberg for your opinions? 23 A. Yes. 24 Yes. 25 Patients WITNESS: 26 A. Yes. 27 BY MR. THORNBURGH: 28 Q. And I want to talk about this in greater detail later on, but the First Human Use Study or the first human study that Ethicon did, when was the interim data available to Ethicon? 28 A. The interim data was looked at two weeks prior to launch.	2 3 4 5 6 7 8 9 10 11 12	study in humans before they launched the TVT-Secur product?  A. There was a study that was started, if I recall, in April of 2006 and prior to launch they had data, five-week data on 31 patients.  Q. Okay. And, so, this document, dated December 2, 2005, was signed prior to the beginning of the clinical study that was done by Ethicon?  A. Yes, based on my understanding.  Q. Okay. And the clinical study that was done prior to launch, can you just briefly describe what kind of study that was, how many patients and	2 3 4 5 6 7 8 9 10 11	of the document support your opinions?  A. As of December 2, 2005, Dr. Weisberg had already concluded Dr. Weisberg, the Medical Director at Ethicon, had already concluded that additional clinical studies were not necessary to determine safety and efficacy of the product prior to release.  Q. Do you agree with that determination by Dr. Weisberg?  A. No.  Q. Did Dr. Weisberg sign off on the safety and efficacy of the TVT-Secur product before the
patients that had been treated with the TVT-Secur and had the TVT-Secur in them for five weeks.  17 BY MR. THORNBURGH:  18 Q. Okay. And did you also read the 19 testimony of Dr. Martin Weisberg? 19 detail later on, but the First Human Use Study or 20 A. Yes. 20 the first human study that Ethicon did, when was 21 Q. And did you rely at least in part on the 22 testimony of Dr. Martin Weisberg for your opinions? 23 A. Yes. 24 A. The interim data was looked at two weeks 25 prior to launch.	2 3 4 5 6 7 8 9 10 11 12 13	study in humans before they launched the TVT-Secur product?  A. There was a study that was started, if I recall, in April of 2006 and prior to launch they had data, five-week data on 31 patients.  Q. Okay. And, so, this document, dated December 2, 2005, was signed prior to the beginning of the clinical study that was done by Ethicon?  A. Yes, based on my understanding.  Q. Okay. And the clinical study that was done prior to launch, can you just briefly describe what kind of study that was, how many patients and the duration of the available data at launch?	2 3 4 5 6 7 8 9 10 11 12 13	of the document support your opinions?  A. As of December 2, 2005, Dr. Weisberg had already concluded Dr. Weisberg, the Medical Director at Ethicon, had already concluded that additional clinical studies were not necessary to determine safety and efficacy of the product prior to release.  Q. Do you agree with that determination by Dr. Weisberg?  A. No.  Q. Did Dr. Weisberg sign off on the safety and efficacy of the TVT-Secur product before the clinical data had ever been analyzed?
and had the TVT-Secur in them for five weeks.  Q. Okay. And did you also read the testimony of Dr. Martin Weisberg?  A. Yes.  Q. And I want to talk about this in greater detail later on, but the First Human Use Study or the first human study that Ethicon did, when was the interim data available to Ethicon?  A. Yes.  A. Yes.  A. The interim data was looked at two weeks prior to launch.	2 3 4 5 6 7 8 9 10 11 12 13 14	study in humans before they launched the TVT-Secur product?  A. There was a study that was started, if I recall, in April of 2006 and prior to launch they had data, five-week data on 31 patients.  Q. Okay. And, so, this document, dated December 2, 2005, was signed prior to the beginning of the clinical study that was done by Ethicon?  A. Yes, based on my understanding.  Q. Okay. And the clinical study that was done prior to launch, can you just briefly describe what kind of study that was, how many patients and the duration of the available data at launch?  A. Well, it was a prospective study that	2 3 4 5 6 7 8 9 10 11 12 13 14	of the document support your opinions?  A. As of December 2, 2005, Dr. Weisberg had already concluded Dr. Weisberg, the Medical Director at Ethicon, had already concluded that additional clinical studies were not necessary to determine safety and efficacy of the product prior to release.  Q. Do you agree with that determination by Dr. Weisberg?  A. No.  Q. Did Dr. Weisberg sign off on the safety and efficacy of the TVT-Secur product before the clinical data had ever been analyzed?  MR. SNELL: Object.
Q. Okay. And did you also read the testimony of Dr. Martin Weisberg? 19 detail later on, but the First Human Use Study or 20 A. Yes. 20 the first human study that Ethicon did, when was 21 Q. And did you rely at least in part on the 22 testimony of Dr. Martin Weisberg for your opinions? 22 A. The interim data was looked at two weeks 23 A. Yes. 23 prior to launch.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	study in humans before they launched the TVT-Secur product?  A. There was a study that was started, if I recall, in April of 2006 and prior to launch they had data, five-week data on 31 patients.  Q. Okay. And, so, this document, dated December 2, 2005, was signed prior to the beginning of the clinical study that was done by Ethicon?  A. Yes, based on my understanding.  Q. Okay. And the clinical study that was done prior to launch, can you just briefly describe what kind of study that was, how many patients and the duration of the available data at launch?  A. Well, it was a prospective study that was done at several centers and they had data on 31	2 3 4 5 6 7 8 9 10 11 12 13 14 15	of the document support your opinions?  A. As of December 2, 2005, Dr. Weisberg had already concluded Dr. Weisberg, the Medical Director at Ethicon, had already concluded that additional clinical studies were not necessary to determine safety and efficacy of the product prior to release.  Q. Do you agree with that determination by Dr. Weisberg?  A. No.  Q. Did Dr. Weisberg sign off on the safety and efficacy of the TVT-Secur product before the clinical data had ever been analyzed?  MR. SNELL: Object. BY THE WITNESS:
testimony of Dr. Martin Weisberg?  A. Yes.  Q. And did you rely at least in part on the testimony of Dr. Martin Weisberg for your opinions?  A. Yes.  19 detail later on, but the First Human Use Study or the first human study that Ethicon did, when was the interim data available to Ethicon?  A. The interim data was looked at two weeks prior to launch.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	study in humans before they launched the TVT-Secur product?  A. There was a study that was started, if I recall, in April of 2006 and prior to launch they had data, five-week data on 31 patients.  Q. Okay. And, so, this document, dated December 2, 2005, was signed prior to the beginning of the clinical study that was done by Ethicon?  A. Yes, based on my understanding.  Q. Okay. And the clinical study that was done prior to launch, can you just briefly describe what kind of study that was, how many patients and the duration of the available data at launch?  A. Well, it was a prospective study that was done at several centers and they had data on 31 patients that had been treated with the TVT-Secur	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	of the document support your opinions?  A. As of December 2, 2005, Dr. Weisberg had already concluded Dr. Weisberg, the Medical Director at Ethicon, had already concluded that additional clinical studies were not necessary to determine safety and efficacy of the product prior to release.  Q. Do you agree with that determination by Dr. Weisberg?  A. No.  Q. Did Dr. Weisberg sign off on the safety and efficacy of the TVT-Secur product before the clinical data had ever been analyzed?  MR. SNELL: Object.  BY THE WITNESS:  A. Yes.
20 A. Yes. 21 Q. And did you rely at least in part on the 22 testimony of Dr. Martin Weisberg for your opinions? 23 A. Yes. 20 the first human study that Ethicon did, when was 21 the interim data available to Ethicon? 22 A. The interim data was looked at two weeks 23 prior to launch.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	study in humans before they launched the TVT-Secur product?  A. There was a study that was started, if I recall, in April of 2006 and prior to launch they had data, five-week data on 31 patients.  Q. Okay. And, so, this document, dated December 2, 2005, was signed prior to the beginning of the clinical study that was done by Ethicon?  A. Yes, based on my understanding.  Q. Okay. And the clinical study that was done prior to launch, can you just briefly describe what kind of study that was, how many patients and the duration of the available data at launch?  A. Well, it was a prospective study that was done at several centers and they had data on 31 patients that had been treated with the TVT-Secur and had the TVT-Secur in them for five weeks.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	of the document support your opinions?  A. As of December 2, 2005, Dr. Weisberg had already concluded Dr. Weisberg, the Medical Director at Ethicon, had already concluded that additional clinical studies were not necessary to determine safety and efficacy of the product prior to release.  Q. Do you agree with that determination by Dr. Weisberg?  A. No.  Q. Did Dr. Weisberg sign off on the safety and efficacy of the TVT-Secur product before the clinical data had ever been analyzed?  MR. SNELL: Object. BY THE WITNESS:  A. Yes. BY MR. THORNBURGH:
Q. And did you rely at least in part on the testimony of Dr. Martin Weisberg for your opinions?  A. Yes.  21 the interim data available to Ethicon?  A. The interim data was looked at two weeks prior to launch.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	study in humans before they launched the TVT-Secur product?  A. There was a study that was started, if I recall, in April of 2006 and prior to launch they had data, five-week data on 31 patients.  Q. Okay. And, so, this document, dated December 2, 2005, was signed prior to the beginning of the clinical study that was done by Ethicon?  A. Yes, based on my understanding.  Q. Okay. And the clinical study that was done prior to launch, can you just briefly describe what kind of study that was, how many patients and the duration of the available data at launch?  A. Well, it was a prospective study that was done at several centers and they had data on 31 patients that had been treated with the TVT-Secur and had the TVT-Secur in them for five weeks.  Q. Okay. And did you also read the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	of the document support your opinions?  A. As of December 2, 2005, Dr. Weisberg had already concluded Dr. Weisberg, the Medical Director at Ethicon, had already concluded that additional clinical studies were not necessary to determine safety and efficacy of the product prior to release.  Q. Do you agree with that determination by Dr. Weisberg?  A. No.  Q. Did Dr. Weisberg sign off on the safety and efficacy of the TVT-Secur product before the clinical data had ever been analyzed?  MR. SNELL: Object. BY THE WITNESS:  A. Yes. BY MR. THORNBURGH: Q. And I want to talk about this in greater
testimony of Dr. Martin Weisberg for your opinions?  22 A. The interim data was looked at two weeks  23 A. Yes.  22 prior to launch.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	study in humans before they launched the TVT-Secur product?  A. There was a study that was started, if I recall, in April of 2006 and prior to launch they had data, five-week data on 31 patients.  Q. Okay. And, so, this document, dated December 2, 2005, was signed prior to the beginning of the clinical study that was done by Ethicon?  A. Yes, based on my understanding.  Q. Okay. And the clinical study that was done prior to launch, can you just briefly describe what kind of study that was, how many patients and the duration of the available data at launch?  A. Well, it was a prospective study that was done at several centers and they had data on 31 patients that had been treated with the TVT-Secur and had the TVT-Secur in them for five weeks.  Q. Okay. And did you also read the testimony of Dr. Martin Weisberg?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	of the document support your opinions?  A. As of December 2, 2005, Dr. Weisberg had already concluded Dr. Weisberg, the Medical Director at Ethicon, had already concluded that additional clinical studies were not necessary to determine safety and efficacy of the product prior to release.  Q. Do you agree with that determination by Dr. Weisberg?  A. No.  Q. Did Dr. Weisberg sign off on the safety and efficacy of the TVT-Secur product before the clinical data had ever been analyzed?  MR. SNELL: Object. BY THE WITNESS:  A. Yes. BY MR. THORNBURGH:  Q. And I want to talk about this in greater detail later on, but the First Human Use Study or
23 A. Yes. 23 prior to launch.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	study in humans before they launched the TVT-Secur product?  A. There was a study that was started, if I recall, in April of 2006 and prior to launch they had data, five-week data on 31 patients.  Q. Okay. And, so, this document, dated December 2, 2005, was signed prior to the beginning of the clinical study that was done by Ethicon?  A. Yes, based on my understanding.  Q. Okay. And the clinical study that was done prior to launch, can you just briefly describe what kind of study that was, how many patients and the duration of the available data at launch?  A. Well, it was a prospective study that was done at several centers and they had data on 31 patients that had been treated with the TVT-Secur and had the TVT-Secur in them for five weeks.  Q. Okay. And did you also read the testimony of Dr. Martin Weisberg?  A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	of the document support your opinions?  A. As of December 2, 2005, Dr. Weisberg had already concluded Dr. Weisberg, the Medical Director at Ethicon, had already concluded that additional clinical studies were not necessary to determine safety and efficacy of the product prior to release.  Q. Do you agree with that determination by Dr. Weisberg?  A. No.  Q. Did Dr. Weisberg sign off on the safety and efficacy of the TVT-Secur product before the clinical data had ever been analyzed?  MR. SNELL: Object. BY THE WITNESS:  A. Yes. BY MR. THORNBURGH:  Q. And I want to talk about this in greater detail later on, but the First Human Use Study or the first human study that Ethicon did, when was
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24 Q. And if you just turn with me to Bates   24 Q. And do you have an opinion whether or	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	study in humans before they launched the TVT-Secur product?  A. There was a study that was started, if I recall, in April of 2006 and prior to launch they had data, five-week data on 31 patients.  Q. Okay. And, so, this document, dated December 2, 2005, was signed prior to the beginning of the clinical study that was done by Ethicon?  A. Yes, based on my understanding.  Q. Okay. And the clinical study that was done prior to launch, can you just briefly describe what kind of study that was, how many patients and the duration of the available data at launch?  A. Well, it was a prospective study that was done at several centers and they had data on 31 patients that had been treated with the TVT-Secur and had the TVT-Secur in them for five weeks.  Q. Okay. And did you also read the testimony of Dr. Martin Weisberg?  A. Yes.  Q. And did you rely at least in part on the testimony of Dr. Martin Weisberg for your opinions?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	of the document support your opinions?  A. As of December 2, 2005, Dr. Weisberg had already concluded Dr. Weisberg, the Medical Director at Ethicon, had already concluded that additional clinical studies were not necessary to determine safety and efficacy of the product prior to release.  Q. Do you agree with that determination by Dr. Weisberg?  A. No.  Q. Did Dr. Weisberg sign off on the safety and efficacy of the TVT-Secur product before the clinical data had ever been analyzed?  MR. SNELL: Object. BY THE WITNESS:  A. Yes. BY MR. THORNBURGH:  Q. And I want to talk about this in greater detail later on, but the First Human Use Study or the first human study that Ethicon did, when was the interim data available to Ethicon?  A. The interim data was looked at two weeks
	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	study in humans before they launched the TVT-Secur product?  A. There was a study that was started, if I recall, in April of 2006 and prior to launch they had data, five-week data on 31 patients.  Q. Okay. And, so, this document, dated December 2, 2005, was signed prior to the beginning of the clinical study that was done by Ethicon?  A. Yes, based on my understanding.  Q. Okay. And the clinical study that was done prior to launch, can you just briefly describe what kind of study that was, how many patients and the duration of the available data at launch?  A. Well, it was a prospective study that was done at several centers and they had data on 31 patients that had been treated with the TVT-Secur and had the TVT-Secur in them for five weeks.  Q. Okay. And did you also read the testimony of Dr. Martin Weisberg?  A. Yes.  Q. And did you rely at least in part on the testimony of Dr. Martin Weisberg for your opinions?  A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	of the document support your opinions?  A. As of December 2, 2005, Dr. Weisberg had already concluded Dr. Weisberg, the Medical Director at Ethicon, had already concluded that additional clinical studies were not necessary to determine safety and efficacy of the product prior to release.  Q. Do you agree with that determination by Dr. Weisberg?  A. No.  Q. Did Dr. Weisberg sign off on the safety and efficacy of the TVT-Secur product before the clinical data had ever been analyzed?  MR. SNELL: Object. BY THE WITNESS:  A. Yes. BY MR. THORNBURGH:  Q. And I want to talk about this in greater detail later on, but the First Human Use Study or the first human study that Ethicon did, when was the interim data available to Ethicon?  A. The interim data was looked at two weeks prior to launch.

40 (Pages 154 to 157)

	Page 158		Page 160
1	not the first human clinical data interim analysis	1	BY MR. THORNBURGH:
2	supported the safety and efficacy of the TVT-Secur	2	Q. What's that opinion?
3	product?	3	A. That it did not support the safety and
4	A. Yes, I do have an opinion.	4	efficacy of the TVT-Secur.
5	Q. What's that opinion?	5	Q. And why not?
6	A. It did not support the safety and	6	MR. SNELL: Object.
7	efficacy of the TVT-Secur.	7	BY THE WITNESS:
8	Q. Do you have an opinion whether or not	8	A. The failure rate was approximately 30%
9	Ethicon should have conducted a randomized	9	and the complication rate was approximately 60%.
10	controlled trial before signing off on the safety	10	BY MR. THORNBURGH:
11	and efficacy of the TVT-Secur product?	11	Q. Based on your review of Dr. Weisberg's
12	A. Yes, I do have an opinion.	12	Clinical Expert Report and the other interim and
13	Q. What's that opinion?	13	the other internal documents that we'll discuss
14	A. They should have done a randomized	14	today, do you have an opinion whether or not the
15	controlled trial before signing off on the safety	15	clinical study that was done by Ethicon mattered to
16	and efficacy of the product.	16	Dr. Weisberg or the Medical Affairs department in
17	Q. Do you have an opinion whether or not	17	terms of determining whether the TVT-Secur product
18	Ethicon should have at least waited for the	18	was safe and effective?
19	five-week 31 patient interim data before signing	19	MR. SNELL: Object.
20	off on the safety and efficacy of the Ethicon	20	BY THE WITNESS:
21	TVT-Secur product?	21	A. Yes, I do.
22	MR. SNELL: Object.	22	BY MR. THORNBURGH:
	MR. SNELL. Object. BY THE WITNESS:	23	
23		24	Q. What's that opinion?
24	A. Yes, I do have an opinion.	24	A. That it did not seem to be important
	Page 159		Page 161
1	BY MR. THORNBURGH:	1	that that data did not seem to be important in the
2	Q. And what's that opinion?	2	decision whether or not to launch the product.
3	A. That the safety and efficacy the data	3	Q. Other than the five-week 31 patient
4	from the five-week 31 patients should have been an	4	First Human Use interim data, what other studies
5	important consideration to look at prior to signing	5	did Ethicon do in humans, live humans, prior to
6	off on the Clinical Expert Report and deeming that	6	launching the TVT-Secur product?
7	no further safety and efficacy data is necessary	7	MR. SNELL: Object.
8	prior to launch.	8	BY MR. THORNBURGH:
9	Q. And did the interim data from the First	9	Q. Go ahead.
10	Human Use Study, was that available prior to	10	A. None.
11	launch?	11	Q. Did Ethicon do any studies of the
12	A. The interim data, yes.	12	TVT-Secur product prior to launch other than the
13	Q. When did that data become available?	13	interim First Human Use Study?
14	MR. SNELL: Object.	14	A. There was a sheep study that was done in
15	BY THE WITNESS:	15	live sheep that was done in 2004. There was a
16	A. Again, it was looked at two weeks prior	16	sheep cadaver study that was performed in 2005.
17	to launch.	17	And then there were human cadaver studies that
18	BY MR. THORNBURGH:	18	were that were performed.
19	Q. And do you have an opinion whether or	19	Q. Now, the live sheep study, was that done
20	not the interim data supported the safety and	20	on was that study performed using the TVT-Secur
21	efficacy of the TVT-Secur product?	21	product in final form as it was sold to doctors for
	MR. SNELL: Object; repetition.	22	implantation into patients?
22	J y P	1	± **** ****
23	BY THE WITNESS:	23	A. No, it was not.
	BY THE WITNESS:  A. I do have an opinion.	23 24	<ul><li>A. No, it was not.</li><li>Q. What was that what was the strike</li></ul>

41 (Pages 158 to 161)

	Page 162		Page 164
1	that.	1	A. Martin Weisberg.
2	What was the test or tested product in	2	Q. Mark Weisberg. Thank you.
3	the TVT strike that.	3	You've reviewed the testimony of
4	What product was tested in the sheep	4	Dr. Mark
5	study on live sheep?	5	A. Martin.
6	A. It was called the TVT X, which was at	6	Q Martin Weisberg?
7	that point 12 centimeters long and had a different	7	A. Yes.
8	fleece end. The original embodiment had four	8	Q. And did you review strike that.
9	finger projections. During the study they changed	9	Do you have an understanding based on
10	that to three finger projections.	10	your review of Dr. Martin Weisberg's deposition
11	Q. Do you have an opinion whether or not	11	whether or not he understood what the risks were
12	the TVT X live sheep study supported the safety and	12	associated with the TVT-Secur product prior to
13	efficacy of the TVT-Secur product?	13	launch?
14	A. Yes, I do have an opinion.	14	MR. SNELL: Object.
15	Q. What is that opinion?	15	BY THE WITNESS:
16	A. No, it did not support it.	16	A. Yes.
17	Q. Did any of the animal studies, the live	17	BY MR. THORNBURGH:
18	sheep study or the study that was done in sheep	18	Q. I want to do a side-by-side of
19	cadavers, and by cadavers, you understand I mean	19	Exhibit P0871. Do you have P0871?
20	dead sheep, did any of those either of those	20	A. Yes.
21	studies support the safety or efficacy of the	21	
22	TVT-Secur product to be used in human patients?	22	•
23	A. No, it did not.	23	that in front of you?  A. Yes.
		24	
24	Q. Why not?	24	Q. Okay. And if you turn to the to
	Page 163		Page 165
1	A. It was not designed to look at safety	1	ETH.MESH.02340589 of Exhibit P871, you'll see a
2	and effectiveness in the humans of the final	2	"Adverse Reactions" section?
3	product that was sold starting September 20, 2006.	3	A. Yes.
4	Q. Turning back to P1177, if you turn with	4	Q. And does the potential complications
5	me to Bates number ending in 5241, there is a list	5	that were listed by Martin Weisberg in his Clinical
6	of potential complications that are identified.	6	Expert Report dated December 2, 2005 match the
7	Do you see that?	7	"Adverse Reactions" section which made it into the
8	A. Yes.	8	final TVT-Secur IFU?
9	Q. And did Ethicon have any human data	9	A. Yes.
10	related to or specifically related to the TVT-Secur	10	Q. Do you have an opinion whether or not
11	product prior to identifying these potential	11	the "Adverse Reactions" section in the IFU contains
12	complications with the TVT-Secur product?	12	a complete and accurate disclosure of the risks
13	MR. SNELL: Object.	13	that Ethicon knew or should have known about prior
14	BY THE WITNESS:	14	to launching the TVT-Secur product?
15	A. No, they did not.	15	MR. SNELL: Object.
16	BY MR. THORNBURGH:	16	BY THE WITNESS:
	Q. Did Ethicon identify these potential	17	A. Yes, I do have an opinion.
1 1	complications prior to ever conducting a human	18	BY MR. THORNBURGH:
17 18			Q. And what's that opinion?
18		19	
18 19	study?	19	
18 19 20	study? A. A live human study? No.	20	A. It is an incomplete list of all the
18 19 20 21	study?  A. A live human study? No.  Q. And have you also reviewed strike	20 21	A. It is an incomplete list of all the adverse reactions that are associated with the
18 19 20 21 22	study? A. A live human study? No. Q. And have you also reviewed strike that.	20 21 22	A. It is an incomplete list of all the adverse reactions that are associated with the TVT-Secur device.
18 19 20 21	study?  A. A live human study? No.  Q. And have you also reviewed strike	20 21	A. It is an incomplete list of all the adverse reactions that are associated with the

42 (Pages 162 to 165)

	Page 166		Page 168
1	A. Yes.	1	identified in 2377, which were known by him in
2	MR. THORNBURGH: I will hand defense counsel	2	prior to launching the TVT product, could have been
3	P2377. Thank you.	3	added to the TVT IFUs?
4	And if you can, put P2377 side by side	4	MR. SNELL: Object. Object. Go ahead.
5	on the screen with Exhibit P1177, ETH.MESH ending	5	BY THE WITNESS:
6	in 241, and the "Adverse Reactions" section in P871	6	A. These additional adverse reactions could
7	of the IFU ending in Bates No. 589. Can you put	7	have been added to the Instructions for Use.
8	all three of those documents up.	8	BY MR. THORNBURGH:
9	MR. SNELL: Note my objection to P1640.	9	Q. Do you have an opinion whether or not it
10	BY MR. THORNBURGH:	10	would have been reasonable and feasible for Ethicon
11	Q. Doctor, what is P2377?	11	to disclose in the TVT-Secur IFU the adverse
12	A. It is an exhibit from Dr. Weisberg's	12	reactions that are identified in 2377?
13	testimony.	13	MR. SNELL: Object. Go ahead.
14	Q. What did Dr. Weisberg testify to	14	BY THE WITNESS:
15	concerning Exhibit P2377?	15	A. Yes, I have an opinion.
16	MR. SNELL: Object.	16	BY MR. THORNBURGH:
17	BY THE WITNESS:	17	Q. What's that opinion?
18	A. That these were adverse reactions that	18	A. That it would have been reasonable and
19	were known since the time of launch of the TVT	19	feasible to add these to the Instructions for Use.
20	device.	20	Q. And the did Ethicon include the
21	BY MR. THORNBURGH:	21	adverse reactions that Weisberg testified he knew
22	Q. And when was the TVT device launched?	22	of and were would have been feasible and
23	A. Either the end of very end of 1997 or	23	reasonable in to add to strike that.
24	very early in 1998.	24	Did Dr did Ethicon include the
			2.0 2.1 Old Zameon method and
	Daga 167		
	Page 167		Page 169
1	Q. And, so, this was six years or eight	1	Page 169 adverse reactions identified in P2377 within the
1 2		1 2	
	Q. And, so, this was six years or eight		adverse reactions identified in P2377 within the
2	Q. And, so, this was six years or eight years prior to launching the TVT-Secur product?	2	adverse reactions identified in P2377 within the TVT-Secur IFU?
2 3	<ul><li>Q. And, so, this was six years or eight years prior to launching the TVT-Secur product?</li><li>A. Correct.</li></ul>	2 3	adverse reactions identified in P2377 within the TVT-Secur IFU?  A. No, they never did.
2 3 4	<ul><li>Q. And, so, this was six years or eight years prior to launching the TVT-Secur product?</li><li>A. Correct.</li><li>Q. And what did Dr so, I think you</li></ul>	2 3 4	adverse reactions identified in P2377 within the TVT-Secur IFU?  A. No, they never did.  Q. And are the if we look at P871, which
2 3 4 5	<ul> <li>Q. And, so, this was six years or eight years prior to launching the TVT-Secur product?</li> <li>A. Correct.</li> <li>Q. And what did Dr so, I think you testified I'm going to read back, make sure I've</li> </ul>	2 3 4 5	adverse reactions identified in P2377 within the TVT-Secur IFU?  A. No, they never did.  Q. And are the if we look at P871, which is the TVT-Secur IFU, Bates No. 589, are these the
2 3 4 5 6	<ul> <li>Q. And, so, this was six years or eight years prior to launching the TVT-Secur product?</li> <li>A. Correct.</li> <li>Q. And what did Dr so, I think you testified I'm going to read back, make sure I've got it here but you've testified that</li> </ul>	2 3 4 5 6	adverse reactions identified in P2377 within the TVT-Secur IFU?  A. No, they never did.  Q. And are the if we look at P871, which is the TVT-Secur IFU, Bates No. 589, are these the adverse reactions that Ethicon put into the
2 3 4 5 6 7	<ul> <li>Q. And, so, this was six years or eight years prior to launching the TVT-Secur product?</li> <li>A. Correct.</li> <li>Q. And what did Dr so, I think you testified I'm going to read back, make sure I've got it here but you've testified that</li> <li>Exhibit 2377 reflects the adverse reactions that</li> </ul>	2 3 4 5 6 7	adverse reactions identified in P2377 within the TVT-Secur IFU?  A. No, they never did.  Q. And are the if we look at P871, which is the TVT-Secur IFU, Bates No. 589, are these the adverse reactions that Ethicon put into the TVT-Secur IFU back in 2006 when they launched the
2 3 4 5 6 7 8	<ul> <li>Q. And, so, this was six years or eight years prior to launching the TVT-Secur product?</li> <li>A. Correct.</li> <li>Q. And what did Dr so, I think you testified I'm going to read back, make sure I've got it here but you've testified that</li> <li>Exhibit 2377 reflects the adverse reactions that were known since the time of launch of the</li> </ul>	2 3 4 5 6 7 8	adverse reactions identified in P2377 within the TVT-Secur IFU?  A. No, they never did. Q. And are the if we look at P871, which is the TVT-Secur IFU, Bates No. 589, are these the adverse reactions that Ethicon put into the TVT-Secur IFU back in 2006 when they launched the TVT-Secur product?
2 3 4 5 6 7 8	Q. And, so, this was six years or eight years prior to launching the TVT-Secur product?  A. Correct.  Q. And what did Dr so, I think you testified I'm going to read back, make sure I've got it here but you've testified that Exhibit 2377 reflects the adverse reactions that were known since the time of launch of the TVT-Secur device. Is that your testimony?	2 3 4 5 6 7 8	adverse reactions identified in P2377 within the TVT-Secur IFU?  A. No, they never did.  Q. And are the if we look at P871, which is the TVT-Secur IFU, Bates No. 589, are these the adverse reactions that Ethicon put into the TVT-Secur IFU back in 2006 when they launched the TVT-Secur product?  A. Yes.
2 3 4 5 6 7 8 9	Q. And, so, this was six years or eight years prior to launching the TVT-Secur product?  A. Correct.  Q. And what did Dr so, I think you testified I'm going to read back, make sure I've got it here but you've testified that Exhibit 2377 reflects the adverse reactions that were known since the time of launch of the TVT-Secur device. Is that your testimony?  MR. SNELL: Object.	2 3 4 5 6 7 8 9	adverse reactions identified in P2377 within the TVT-Secur IFU?  A. No, they never did.  Q. And are the if we look at P871, which is the TVT-Secur IFU, Bates No. 589, are these the adverse reactions that Ethicon put into the TVT-Secur IFU back in 2006 when they launched the TVT-Secur product?  A. Yes.  Q. Did Ethicon ever change the IFU section
2 3 4 5 6 7 8 9 10	Q. And, so, this was six years or eight years prior to launching the TVT-Secur product?  A. Correct.  Q. And what did Dr so, I think you testified I'm going to read back, make sure I've got it here but you've testified that  Exhibit 2377 reflects the adverse reactions that were known since the time of launch of the TVT-Secur device. Is that your testimony?  MR. SNELL: Object.  BY THE WITNESS:	2 3 4 5 6 7 8 9 10	adverse reactions identified in P2377 within the TVT-Secur IFU?  A. No, they never did.  Q. And are the if we look at P871, which is the TVT-Secur IFU, Bates No. 589, are these the adverse reactions that Ethicon put into the TVT-Secur IFU back in 2006 when they launched the TVT-Secur product?  A. Yes.  Q. Did Ethicon ever change the IFU section on adverse reactions from the time they launched
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MR. SNELL: Object. Y THE WITNESS:  A. Because these are adverse reactions that re-have been known to be associated with the VT-Secur device. That information should be given a physicians in the Instructions for Use. The astructions for Use should include all of the astructions for Use should include all of the astructions for Use should not own risks associated with the device.  The Instructions for Use should not ownplay the risks associated with the device or oscure risks that are associated with the device acause doctors have different treatments and evices that they can use to treat a particular condition and patients have choices about the type of surgeries they have and the type of devices that re used to treat medical conditions and doctors annot have an informed decision with a with a oman if they are not aware of all the potential diverse reactions associated with the device.	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	data from the First Human Use Study in the "Warnings" section of the IFU for the TVT-Secur before they launched the product? MR. SNELL: Object. BY THE WITNESS: A. Yes, the Instructions for Use should include the frequency, severity, treatability and permanency of adverse reactions that were associated with a device. BY MR. THORNBURGH: Q. If manufacturing companies like Ethicon do you have an opinion whether or not manufacturers do you have an opinion whether or not medical device manufacturers such as Ethicon and Johnson & Johnson should be complete and accurate in their disclosure of safety information? A. Yes, I have an opinion.
A. Because these are adverse reactions that re have been known to be associated with the VT-Secur device. That information should be given rephysicians in the Instructions for Use. The structions for Use should include all of the nown risks associated with the device.  The Instructions for Use should not rephysicians that are associated with the device or rescure risks that are associated with the device or rescure risks that are associated with the device recause doctors have different treatments and revices that they can use to treat a particular rendition and patients have choices about the type of surgeries they have and the type of devices that re used to treat medical conditions and doctors annot have an informed decision with a with a recommend they are not aware of all the potential	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	before they launched the product?  MR. SNELL: Object. BY THE WITNESS:  A. Yes, the Instructions for Use should include the frequency, severity, treatability and permanency of adverse reactions that were associated with a device. BY MR. THORNBURGH:  Q. If manufacturing companies like Ethicon do you have an opinion whether or not manufacturers do you have an opinion whether or not medical device manufacturers such as Ethicon and Johnson & Johnson should be complete and accurate in their disclosure of safety information?
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VT-Secur device. That information should be given a physicians in the Instructions for Use. The astructions for Use should include all of the astructions for Use should include all of the above risks associated with the device.  The Instructions for Use should not ownplay the risks associated with the device or oscure risks that are associated with the device occause doctors have different treatments and evices that they can use to treat a particular ondition and patients have choices about the type of surgeries they have and the type of devices that the used to treat medical conditions and doctors annot have an informed decision with a with a coman if they are not aware of all the potential	5 6 7 8 9 10 11 12 13 14 15 16 17	BY THE WITNESS:  A. Yes, the Instructions for Use should include the frequency, severity, treatability and permanency of adverse reactions that were associated with a device.  BY MR. THORNBURGH:  Q. If manufacturing companies like  Ethicon do you have an opinion whether or not manufacturers do you have an opinion whether or not medical device manufacturers such as Ethicon and Johnson & Johnson should be complete and accurate in their disclosure of safety information?
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astructions for Use should include all of the nown risks associated with the device.  The Instructions for Use should not ownplay the risks associated with the device or oscure risks that are associated with the device ecause doctors have different treatments and evices that they can use to treat a particular ondition and patients have choices about the type of surgeries they have and the type of devices that the used to treat medical conditions and doctors annot have an informed decision with a with a coman if they are not aware of all the potential	7 8 9 10 11 12 13 14 15 16 17	include the frequency, severity, treatability and permanency of adverse reactions that were associated with a device.  BY MR. THORNBURGH:  Q. If manufacturing companies like Ethicon do you have an opinion whether or not manufacturers do you have an opinion whether or not medical device manufacturers such as Ethicon and Johnson & Johnson should be complete and accurate in their disclosure of safety information?
The Instructions for Use should not ownplay the risks associated with the device or oscure risks that are associated with the device ecause doctors have different treatments and evices that they can use to treat a particular ondition and patients have choices about the type of surgeries they have and the type of devices that the used to treat medical conditions and doctors annot have an informed decision with a with a coman if they are not aware of all the potential	8 9 10 11 12 13 14 15 16 17	permanency of adverse reactions that were associated with a device. BY MR. THORNBURGH: Q. If manufacturing companies like Ethicon do you have an opinion whether or not manufacturers do you have an opinion whether or not medical device manufacturers such as Ethicon and Johnson & Johnson should be complete and accurate in their disclosure of safety information?
The Instructions for Use should not ownplay the risks associated with the device or oscure risks that are associated with the device ecause doctors have different treatments and evices that they can use to treat a particular ondition and patients have choices about the type of devices that the used to treat medical conditions and doctors annot have an informed decision with a with a coman if they are not aware of all the potential	9 10 11 12 13 14 15 16 17	associated with a device.  BY MR. THORNBURGH:  Q. If manufacturing companies like  Ethicon do you have an opinion whether or not manufacturers do you have an opinion whether or not medical device manufacturers such as Ethicon and Johnson & Johnson should be complete and accurate in their disclosure of safety information?
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escure risks that are associated with the device ecause doctors have different treatments and evices that they can use to treat a particular ondition and patients have choices about the type of surgeries they have and the type of devices that the used to treat medical conditions and doctors annot have an informed decision with a with a coman if they are not aware of all the potential	11 12 13 14 15 16 17 18	Q. If manufacturing companies like Ethicon do you have an opinion whether or not manufacturers do you have an opinion whether or not medical device manufacturers such as Ethicon and Johnson & Johnson should be complete and accurate in their disclosure of safety information?
ecause doctors have different treatments and evices that they can use to treat a particular ondition and patients have choices about the type of surgeries they have and the type of devices that the used to treat medical conditions and doctors annot have an informed decision with a with a coman if they are not aware of all the potential	12 13 14 15 16 17 18	Ethicon do you have an opinion whether or not manufacturers do you have an opinion whether or not medical device manufacturers such as Ethicon and Johnson & Johnson should be complete and accurate in their disclosure of safety information?
evices that they can use to treat a particular ondition and patients have choices about the type of surgeries they have and the type of devices that we used to treat medical conditions and doctors annot have an informed decision with a with a coman if they are not aware of all the potential	13 14 15 16 17 18	manufacturers do you have an opinion whether or not medical device manufacturers such as Ethicon and Johnson & Johnson should be complete and accurate in their disclosure of safety information?
ondition and patients have choices about the type of surgeries they have and the type of devices that the used to treat medical conditions and doctors annot have an informed decision with a with a coman if they are not aware of all the potential	14 15 16 17 18	not medical device manufacturers such as Ethicon and Johnson & Johnson should be complete and accurate in their disclosure of safety information?
r surgeries they have and the type of devices that re used to treat medical conditions and doctors annot have an informed decision with a with a oman if they are not aware of all the potential	15 16 17 18	and Johnson & Johnson should be complete and accurate in their disclosure of safety information?
re used to treat medical conditions and doctors annot have an informed decision with a with a oman if they are not aware of all the potential	16 17 18	accurate in their disclosure of safety information?
re used to treat medical conditions and doctors annot have an informed decision with a with a oman if they are not aware of all the potential	17 18	
oman if they are not aware of all the potential	18	A. Yes, I have an opinion.
lverse reactions associated with the device.	19	Q. Do you have an opinion whether or not
		manufacturers like Ethicon and Johnson & Johnson
Y MR. THORNBURGH:	20	should be complete and accurate in their disclosure
Q. Did Ethicon ever change the list of	21	of efficacy information?
otential complications that they identified in the	22	A. Yes, I have an opinion.
ecember 2005 Clinical Expert Report until the date	23	Q. And what are the what are your
at they launched the TVT-Secur on the product	24	opinions with respect to both safety and efficacy?
n to the market in September of 2006?	1	A. That they should
A. No, they did not.	2	MR. SNELL: Object. Go ahead.
Q. Would it have been reasonable and	3	BY THE WITNESS:
easible for Ethicon to make revisions to those	4	A. They should disclose all the safety and
otential complications?	5	efficacy information that they have available to
MR. SNELL: Object. Go ahead.	6	them.
Y THE WITNESS:	7	BY MR. THORNBURGH:
A. Yes.	8	Q. As a physician treating patients and
Y MR. THORNBURGH:	9	discussing with patients surgical options for the
Q. Did Ethicon have human data from their	10	treatment of stress urinary incontinence, would you
irst Human Use Study that they could have looked	11	have expected Ethicon to disclose to you in their
to determine whether or not changes could	12	IFU or otherwise that their First Human Use Study
ave could or should have been made to the	13	demonstrated that 60% of the patients could
		experience or were at risk of experiencing
		complications?
VT-Secur "Adverse Reactions" section in the IFU?	16	MR. SNELL: Object.
VT-Secur "Adverse Reactions" section in the IFU? A. Yes.	17	BY MR. THORNBURGH:
VT-Secur "Adverse Reactions" section in the IFU? A. Yes. Q. And what was that exactly?	18	Q. From the TVT-Secur product.
VT-Secur "Adverse Reactions" section in the IFU? A. Yes. Q. And what was that exactly? MR. SNELL: Object.		A. Yes, I would have expected them to
VT-Secur "Adverse Reactions" section in the IFU? A. Yes. Q. And what was that exactly? MR. SNELL: Object. Y THE WITNESS:	19	disclose that.
VT-Secur "Adverse Reactions" section in the IFU? A. Yes. Q. And what was that exactly? MR. SNELL: Object. Y THE WITNESS: A. They had the First Human Use data,	19 20	
VT-Secur "Adverse Reactions" section in the IFU? A. Yes. Q. And what was that exactly? MR. SNELL: Object. Y THE WITNESS: A. They had the First Human Use data, gain, that showed a 30% failure rate and a 60%		Q. As a physician treating patients and
VT-Secur "Adverse Reactions" section in the IFU? A. Yes. Q. And what was that exactly? MR. SNELL: Object. Y THE WITNESS: A. They had the First Human Use data,	20	Q. As a physician treating patients and discussing with patients surgical options for the
VT-Secur "Adverse Reactions" section in the IFU? A. Yes. Q. And what was that exactly? MR. SNELL: Object. Y THE WITNESS: A. They had the First Human Use data, gain, that showed a 30% failure rate and a 60% complication rate.	20 21	Q. As a physician treating patients and discussing with patients surgical options for the treatment of stress urinary incontinence, would you
	T-Secur "Adverse Reactions" section in the IFU? A. Yes. Q. And what was that exactly? MR. SNELL: Object. THE WITNESS:	T-Secur "Adverse Reactions" section in the IFU?  A. Yes.  Q. And what was that exactly?  MR. SNELL: Object.  THE WITNESS:  A. They had the First Human Use data,

	Page 174		Page 176
1	IFU or otherwise that the First Human Use Study	1	A. Yes, I have an opinion.
2	demonstrated a 30% failure rate?	2	BY MR. THORNBURGH:
3	MR. SNELL: Object.	3	Q. What's that opinion?
4	BY THE WITNESS:	4	A. It put patients at risk.
5	A. Yes.	5	Q. Do you have an opinion whether or not it
6	BY MR. THORNBURGH:	6	was appropriate for Ethicon or Johnson & Johnson to
7	Q. And what is that opinion?	7	withhold the safety and efficacy data from
8	A. I would have expected that they would	8	physicians concerning the data they had prior to
9	have disclosed that.	9	launch that they received from the First Human Use
10	Q. Why would you have expected as a doctor	10	Study?
11	treating patients that Ethicon would disclose that	11	MR. SNELL: Object.
12	information to you?	12	BY THE WITNESS:
13	MR. SNELL: Continuing objection.	13	A. Yes, I have an opinion.
14	BY THE WITNESS:	14	BY MR. THORNBURGH:
15	A. Because that is information that is	15	Q. What's that opinion?
16	important for me to have so I can have a discussion	16	A. That that information should not have
17	with the patient regarding the safety and efficacy	17	been withheld from physicians.
18	of a given device because doctors have multiple	18	Q. What's the next document in your binder,
19	devices at their disposable at their disposal to	19	Dr. Rosenzweig, that you'd like to discuss?
20	treat conditions or have different surgical	20	A. P0279.
21	procedures that can treat a medical condition and	21	Q. And can you identify what P0279 is?
22	they need all the information about a particular	22	A. Yes.
23	device or procedure at their disposal to decide	23	MR. SNELL: Can I have a copy.
24	whether or not they are going to offer that to an	24	BY THE WITNESS:
	Page 175		Page 177
1	individual patient and the individual patient needs	1	A. It is an e-mail between Gary Borkes, who
2	that information to decide if they want that	2	we've discussed earlier, and Mark Yale, who is a
3	individual treatment.	3	safety officer at Ethicon, describing the TVT
4	BY MR. THORNBURGH:	4	design review, design validation from February 9,
5	Q. Why does any of this matter, Doctor?	5	2006.
6	A. It matters for patient	6	BY MR. THORNBURGH:
7	MR. SNELL: Objection.	7	Q. And how is Exhibit P0279 significant, if
8	BY THE WITNESS:	8	at all, to your opinions in this case?
9	<ol> <li>It matters for patient safety.</li> </ol>	9	<ul> <li>A. It is a discussion between key Ethicon</li> </ul>
	DILLE THOUSAND ON		
10	BY MR. THORNBURGH:	10	employees regarding the design validation process
11	Q. What can happen to patients if companies	11	and the about the pressure that they're under to
11 12	Q. What can happen to patients if companies like Ethicon and Johnson & Johnson are not complete	11 12	and the about the pressure that they're under to get the design validation process done and that if
11 12 13	Q. What can happen to patients if companies like Ethicon and Johnson & Johnson are not complete and accurate about the safety and efficacy of	11 12 13	and the about the pressure that they're under to get the design validation process done and that if the design validation process is not done
11 12 13 14	Q. What can happen to patients if companies like Ethicon and Johnson & Johnson are not complete and accurate about the safety and efficacy of permanent implantable devices that they're selling?	11 12 13 14	and the about the pressure that they're under to get the design validation process done and that if the design validation process is not done completely, appropriately and accurately, that
11 12 13 14 15	Q. What can happen to patients if companies like Ethicon and Johnson & Johnson are not complete and accurate about the safety and efficacy of permanent implantable devices that they're selling?  MR. SNELL: Objection.	11 12 13 14 15	and the about the pressure that they're under to get the design validation process done and that if the design validation process is not done completely, appropriately and accurately, that there can be significant consequences associated
11 12 13 14 15 16	Q. What can happen to patients if companies like Ethicon and Johnson & Johnson are not complete and accurate about the safety and efficacy of permanent implantable devices that they're selling?  MR. SNELL: Objection. BY THE WITNESS:	11 12 13 14 15 16	and the about the pressure that they're under to get the design validation process done and that if the design validation process is not done completely, appropriately and accurately, that there can be significant consequences associated with that.
11 12 13 14 15 16 17	Q. What can happen to patients if companies like Ethicon and Johnson & Johnson are not complete and accurate about the safety and efficacy of permanent implantable devices that they're selling?  MR. SNELL: Objection.  BY THE WITNESS:  A. Patients can get harmed.	11 12 13 14 15 16 17	and the about the pressure that they're under to get the design validation process done and that if the design validation process is not done completely, appropriately and accurately, that there can be significant consequences associated with that.  Q. What are some of the reasons why design
11 12 13 14 15 16 17	Q. What can happen to patients if companies like Ethicon and Johnson & Johnson are not complete and accurate about the safety and efficacy of permanent implantable devices that they're selling?  MR. SNELL: Objection.  BY THE WITNESS:  A. Patients can get harmed.  BY MR. THORNBURGH:	11 12 13 14 15 16 17 18	and the about the pressure that they're under to get the design validation process done and that if the design validation process is not done completely, appropriately and accurately, that there can be significant consequences associated with that.  Q. What are some of the reasons why design validation process may not be done appropriately?
11 12 13 14 15 16 17 18	Q. What can happen to patients if companies like Ethicon and Johnson & Johnson are not complete and accurate about the safety and efficacy of permanent implantable devices that they're selling?  MR. SNELL: Objection.  BY THE WITNESS:  A. Patients can get harmed.  BY MR. THORNBURGH:  Q. Do you have an opinion whether or not	11 12 13 14 15 16 17 18	and the about the pressure that they're under to get the design validation process done and that if the design validation process is not done completely, appropriately and accurately, that there can be significant consequences associated with that.  Q. What are some of the reasons why design validation process may not be done appropriately?  A. Can you repeat the question?
11 12 13 14 15 16 17 18 19 20	Q. What can happen to patients if companies like Ethicon and Johnson & Johnson are not complete and accurate about the safety and efficacy of permanent implantable devices that they're selling?  MR. SNELL: Objection.  BY THE WITNESS:  A. Patients can get harmed.  BY MR. THORNBURGH:  Q. Do you have an opinion whether or not Johnson & Johnson and Ethicon's failure to disclose	11 12 13 14 15 16 17 18 19 20	and the about the pressure that they're under to get the design validation process done and that if the design validation process is not done completely, appropriately and accurately, that there can be significant consequences associated with that.  Q. What are some of the reasons why design validation process may not be done appropriately?  A. Can you repeat the question?  Q. Yes, sure. What are some of the reasons
11 12 13 14 15 16 17 18 19 20 21	Q. What can happen to patients if companies like Ethicon and Johnson & Johnson are not complete and accurate about the safety and efficacy of permanent implantable devices that they're selling?  MR. SNELL: Objection.  BY THE WITNESS:  A. Patients can get harmed.  BY MR. THORNBURGH:  Q. Do you have an opinion whether or not Johnson & Johnson and Ethicon's failure to disclose the safety and efficacy data from the First Human	11 12 13 14 15 16 17 18 19 20 21	and the about the pressure that they're under to get the design validation process done and that if the design validation process is not done completely, appropriately and accurately, that there can be significant consequences associated with that.  Q. What are some of the reasons why design validation process may not be done appropriately?  A. Can you repeat the question?  Q. Yes, sure. What are some of the reasons why a design validation process or study may not
11 12 13 14 15 16 17 18 19 20 21 22	Q. What can happen to patients if companies like Ethicon and Johnson & Johnson are not complete and accurate about the safety and efficacy of permanent implantable devices that they're selling?  MR. SNELL: Objection.  BY THE WITNESS:  A. Patients can get harmed.  BY MR. THORNBURGH:  Q. Do you have an opinion whether or not Johnson & Johnson and Ethicon's failure to disclose the safety and efficacy data from the First Human Use Study put patients at risk of suffering harm?	11 12 13 14 15 16 17 18 19 20 21 22	and the about the pressure that they're under to get the design validation process done and that if the design validation process is not done completely, appropriately and accurately, that there can be significant consequences associated with that.  Q. What are some of the reasons why design validation process may not be done appropriately?  A. Can you repeat the question?  Q. Yes, sure. What are some of the reasons why a design validation process or study may not get done appropriately?
11 12 13 14 15 16 17 18 19 20 21 22 23	Q. What can happen to patients if companies like Ethicon and Johnson & Johnson are not complete and accurate about the safety and efficacy of permanent implantable devices that they're selling?  MR. SNELL: Objection.  BY THE WITNESS:  A. Patients can get harmed.  BY MR. THORNBURGH:  Q. Do you have an opinion whether or not Johnson & Johnson and Ethicon's failure to disclose the safety and efficacy data from the First Human Use Study put patients at risk of suffering harm?  MR. SNELL: Objection.	11 12 13 14 15 16 17 18 19 20 21 22 23	and the about the pressure that they're under to get the design validation process done and that if the design validation process is not done completely, appropriately and accurately, that there can be significant consequences associated with that.  Q. What are some of the reasons why design validation process may not be done appropriately?  A. Can you repeat the question?  Q. Yes, sure. What are some of the reasons why a design validation process or study may not get done appropriately?  MR. SNELL: Objection.
11 12 13 14 15 16 17 18 19 20 21 22	Q. What can happen to patients if companies like Ethicon and Johnson & Johnson are not complete and accurate about the safety and efficacy of permanent implantable devices that they're selling?  MR. SNELL: Objection.  BY THE WITNESS:  A. Patients can get harmed.  BY MR. THORNBURGH:  Q. Do you have an opinion whether or not Johnson & Johnson and Ethicon's failure to disclose the safety and efficacy data from the First Human Use Study put patients at risk of suffering harm?	11 12 13 14 15 16 17 18 19 20 21 22	and the about the pressure that they're under to get the design validation process done and that if the design validation process is not done completely, appropriately and accurately, that there can be significant consequences associated with that.  Q. What are some of the reasons why design validation process may not be done appropriately?  A. Can you repeat the question?  Q. Yes, sure. What are some of the reasons why a design validation process or study may not get done appropriately?

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1	A. If there's pressure to get a project	1	MR. SNELL: Object.
2	completed quickly, then a design validation process	2	BY THE WITNESS:
3	might not be done as completely and accurately due	3	A. This supports my opinions that the
4	to time constraints.	4	design validation process was rushed; that all the
5	BY MR. THORNBURGH:	5	characteristics of the TVT-Secur device that were
6	Q. Do you have an opinion whether or not	6	unreasonably unsafe, which led to complications,
7	Ethicon's design validation process was done	7	adverse events and harm to patients, were not
8	appropriately?	8	identified prior to launch; that the design
9	A. Yes, I have an opinion.	9	characteristics that made it unreasonably
10	Q. What's that opinion?	10	ineffective and led to recurrence or inability to
11	MR. SNELL: Object.	11	treat stress incontinence were not found before
12	BY THE WITNESS:	12	launch; and that there was intense pressure from
13	A. It was not done completely and	13	the president down through the ranks to speed the
14	appropriately.	14	process along as quickly as possible to get the
15	BY MR. THORNBURGH:	15	product on the market.
16	Q. Do you have an opinion whether or not	16	Q. You just said a lot. So, I want to
17	Ethicon's do you have a strike that.	17	break that down, and here's how I want to do it.
18	Do you have an opinion why that	18	How would you describe the opinion that
19	occurred, based on your review of Ethicon's	19	you just expressed in one sentence?
20	documents?	20	MR. SNELL: Objection.
21	A. That there was immense pressure to move	21	BY THE WITNESS:
22	the process along so that they could get the	22	A. There was intense pressure to get the
23	product launched as quickly as they as they	23	product to market.
24	could.	24	BY MR. THORNBURGH:
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			1490 101
1	Q. And if we look at Exhibit P0279, I want	1	Q. And the e-mail goes on by Mark Yale and
1 2	to look direct your attention to the bottom half	1 2	Q. And the e-mail goes on by Mark Yale and says, "Bottom line if there is a big steaming pile
	to look direct your attention to the bottom half of the first page, the e-mail from Mark Yale.		Q. And the e-mail goes on by Mark Yale and says, "Bottom line if there is a big steaming pile here (as I suspect), I need to know ASAP and push
2	to look direct your attention to the bottom half of the first page, the e-mail from Mark Yale.  Do you see that?	2	Q. And the e-mail goes on by Mark Yale and says, "Bottom line if there is a big steaming pile here (as I suspect), I need to know ASAP and push back hard on whomever to fix."
2	to look direct your attention to the bottom half of the first page, the e-mail from Mark Yale.  Do you see that?  A. Yes.	2 3	Q. And the e-mail goes on by Mark Yale and says, "Bottom line if there is a big steaming pile here (as I suspect), I need to know ASAP and push back hard on whomever to fix."  Did I read that correctly?
2 3 4	to look direct your attention to the bottom half of the first page, the e-mail from Mark Yale.  Do you see that?  A. Yes.  Q. And is this part of the e-mail that you	2 3 4	Q. And the e-mail goes on by Mark Yale and says, "Bottom line if there is a big steaming pile here (as I suspect), I need to know ASAP and push back hard on whomever to fix."  Did I read that correctly?  MR. SNELL: Object and leading.
2 3 4 5	to look direct your attention to the bottom half of the first page, the e-mail from Mark Yale.  Do you see that?  A. Yes.	2 3 4 5	Q. And the e-mail goes on by Mark Yale and says, "Bottom line if there is a big steaming pile here (as I suspect), I need to know ASAP and push back hard on whomever to fix."  Did I read that correctly?  MR. SNELL: Object and leading. BY THE WITNESS:
2 3 4 5 6	to look direct your attention to the bottom half of the first page, the e-mail from Mark Yale.  Do you see that?  A. Yes.  Q. And is this part of the e-mail that you just discussed?  A. Yes.	2 3 4 5 6 7 8	Q. And the e-mail goes on by Mark Yale and says, "Bottom line if there is a big steaming pile here (as I suspect), I need to know ASAP and push back hard on whomever to fix."  Did I read that correctly?  MR. SNELL: Object and leading. BY THE WITNESS:  A. Yes.
2 3 4 5 6 7	to look direct your attention to the bottom half of the first page, the e-mail from Mark Yale.  Do you see that?  A. Yes.  Q. And is this part of the e-mail that you just discussed?  A. Yes.  Q. And you'll see it says, "Can you give me	2 3 4 5 6 7	Q. And the e-mail goes on by Mark Yale and says, "Bottom line if there is a big steaming pile here (as I suspect), I need to know ASAP and push back hard on whomever to fix."  Did I read that correctly?  MR. SNELL: Object and leading. BY THE WITNESS:  A. Yes. BY MR. THORNBURGH:
2 3 4 5 6 7 8	to look direct your attention to the bottom half of the first page, the e-mail from Mark Yale.  Do you see that?  A. Yes.  Q. And is this part of the e-mail that you just discussed?  A. Yes.  Q. And you'll see it says, "Can you give me insight into where Raimo and Dan are at. For the	2 3 4 5 6 7 8 9	Q. And the e-mail goes on by Mark Yale and says, "Bottom line if there is a big steaming pile here (as I suspect), I need to know ASAP and push back hard on whomever to fix."  Did I read that correctly?  MR. SNELL: Object and leading. BY THE WITNESS:  A. Yes. BY MR. THORNBURGH: Q. How, if at all, does this statement by
2 3 4 5 6 7 8 9 10	to look direct your attention to the bottom half of the first page, the e-mail from Mark Yale.  Do you see that?  A. Yes.  Q. And is this part of the e-mail that you just discussed?  A. Yes.  Q. And you'll see it says, "Can you give me insight into where Raimo and Dan are at. For the last two days at the leadership meeting I had	2 3 4 5 6 7 8 9 10	Q. And the e-mail goes on by Mark Yale and says, "Bottom line if there is a big steaming pile here (as I suspect), I need to know ASAP and push back hard on whomever to fix."  Did I read that correctly?  MR. SNELL: Object and leading. BY THE WITNESS:  A. Yes. BY MR. THORNBURGH: Q. How, if at all, does this statement by Mark Yale support your opinions in this case?
2 3 4 5 6 7 8 9 10 11	to look direct your attention to the bottom half of the first page, the e-mail from Mark Yale.  Do you see that?  A. Yes.  Q. And is this part of the e-mail that you just discussed?  A. Yes.  Q. And you'll see it says, "Can you give me insight into where Raimo and Dan are at. For the last two days at the leadership meeting I had everyone from Renee Selman on down pulling me	2 3 4 5 6 7 8 9 10 11 12	Q. And the e-mail goes on by Mark Yale and says, "Bottom line if there is a big steaming pile here (as I suspect), I need to know ASAP and push back hard on whomever to fix."  Did I read that correctly?  MR. SNELL: Object and leading. BY THE WITNESS:  A. Yes. BY MR. THORNBURGH: Q. How, if at all, does this statement by Mark Yale support your opinions in this case?  MR. SNELL: Object.
2 3 4 5 6 7 8 9 10	to look direct your attention to the bottom half of the first page, the e-mail from Mark Yale.  Do you see that?  A. Yes.  Q. And is this part of the e-mail that you just discussed?  A. Yes.  Q. And you'll see it says, "Can you give me insight into where Raimo and Dan are at. For the last two days at the leadership meeting I had everyone from Renee Selman on down pulling me 'aside' asking me how the proverbial 'we' get this	2 3 4 5 6 7 8 9 10 11 12 13	Q. And the e-mail goes on by Mark Yale and says, "Bottom line if there is a big steaming pile here (as I suspect), I need to know ASAP and push back hard on whomever to fix."  Did I read that correctly?  MR. SNELL: Object and leading. BY THE WITNESS:  A. Yes. BY MR. THORNBURGH: Q. How, if at all, does this statement by Mark Yale support your opinions in this case?  MR. SNELL: Object. BY THE WITNESS:
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	to look direct your attention to the bottom half of the first page, the e-mail from Mark Yale.  Do you see that?  A. Yes.  Q. And is this part of the e-mail that you just discussed?  A. Yes.  Q. And you'll see it says, "Can you give me insight into where Raimo and Dan are at. For the last two days at the leadership meeting I had everyone from Renee Selman on down pulling me 'aside' asking me how the proverbial 'we' get this project done. There is immense political pressure here and I need to actively manage the overall QE response."  Did I read that correctly?  A. Yes.  MR. SNELL: Object; leading. BY MR. THORNBURGH:  Q. First of all, who is Renee Selman?  A. The president of Ethicon.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And the e-mail goes on by Mark Yale and says, "Bottom line if there is a big steaming pile here (as I suspect), I need to know ASAP and push back hard on whomever to fix."  Did I read that correctly?  MR. SNELL: Object and leading.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:  Q. How, if at all, does this statement by Mark Yale support your opinions in this case?  MR. SNELL: Object.  BY THE WITNESS:  A. As of February 9, 2006, it was suspected that there could be design characteristics associated with the device that either made it unreasonably unsafe or led it to be unreasonably ineffective in treating the device; that the head of of quality wanted to know that as soon as possible so that they could find out what those design characteristics were to try to fix those design characteristics to try to make a reasonably
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	to look direct your attention to the bottom half of the first page, the e-mail from Mark Yale.  Do you see that?  A. Yes.  Q. And is this part of the e-mail that you just discussed?  A. Yes.  Q. And you'll see it says, "Can you give me insight into where Raimo and Dan are at. For the last two days at the leadership meeting I had everyone from Renee Selman on down pulling me 'aside' asking me how the proverbial 'we' get this project done. There is immense political pressure here and I need to actively manage the overall QE response."  Did I read that correctly?  A. Yes.  MR. SNELL: Object; leading. BY MR. THORNBURGH:  Q. First of all, who is Renee Selman?  A. The president of Ethicon.  Q. And how does this statement here by Mark	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. And the e-mail goes on by Mark Yale and says, "Bottom line if there is a big steaming pile here (as I suspect), I need to know ASAP and push back hard on whomever to fix."  Did I read that correctly?  MR. SNELL: Object and leading.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:  Q. How, if at all, does this statement by Mark Yale support your opinions in this case?  MR. SNELL: Object.  BY THE WITNESS:  A. As of February 9, 2006, it was suspected that there could be design characteristics associated with the device that either made it unreasonably unsafe or led it to be unreasonably ineffective in treating the device; that the head of of quality wanted to know that as soon as possible so that they could find out what those design characteristics were to try to fix those design characteristics to try to make a reasonably safe and effective device.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	to look direct your attention to the bottom half of the first page, the e-mail from Mark Yale.  Do you see that?  A. Yes.  Q. And is this part of the e-mail that you just discussed?  A. Yes.  Q. And you'll see it says, "Can you give me insight into where Raimo and Dan are at. For the last two days at the leadership meeting I had everyone from Renee Selman on down pulling me 'aside' asking me how the proverbial 'we' get this project done. There is immense political pressure here and I need to actively manage the overall QE response."  Did I read that correctly?  A. Yes.  MR. SNELL: Object; leading. BY MR. THORNBURGH:  Q. First of all, who is Renee Selman?  A. The president of Ethicon.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And the e-mail goes on by Mark Yale and says, "Bottom line if there is a big steaming pile here (as I suspect), I need to know ASAP and push back hard on whomever to fix."  Did I read that correctly?  MR. SNELL: Object and leading.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:  Q. How, if at all, does this statement by Mark Yale support your opinions in this case?  MR. SNELL: Object.  BY THE WITNESS:  A. As of February 9, 2006, it was suspected that there could be design characteristics associated with the device that either made it unreasonably unsafe or led it to be unreasonably ineffective in treating the device; that the head of of quality wanted to know that as soon as possible so that they could find out what those design characteristics were to try to fix those design characteristics to try to make a reasonably

problems associated with the device design,  14 characteristics that are unreasonably unsafe or  15 make it unreasonably ineffective, and that they  16 are those are being ignored and a product is  17 being rushed to market.  18 Q. Did Ethicon ever fix any of the problems  19 with their design validation?  20 MR. SNELL: Objection.  13 TVT-Secur launched?  14 MR. SNELL: Objection.  15 BY THE WITNESS:  16 A. Can you repeat the question again.  17 BY MR. THORNBURGH:  18 Q. Yeah, no problem, no problem. That's  19 probably why it was objected to.  20 Do you know whether or not the document.		Page 182		Page 184
a companies like Ethicon and Johnson & Johnson than what is being described here in this document?  MR. SNELL: Object.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:  Q. What's that opinion?  A. That they do deserve better  consideration than just top executives at Ethicon discussing that there are more likely than not big political pressure on employees in order to get the characteristics that are unreasonably unsafe or make it unreasonably ineffective, and that they are those are being ignored and a product is being rushed to market.  Q. Dia you have an opinion based on your review of the medical – review of Ethicon's internal documents the purpose for putting political pressure on employees in order to get the Type of the medical – review of Ethicon's internal documents the purpose for putting political pressure on employees in order to get the Type of the market first played a role in Ethicon's executives putting political pressure on its employees to get the Type of the documents.  MR. SNELL: Objection.  BY THE WITNESS:  A. They should not be doing that.  Q. Do you have an opinion based on your review of the market first played in the product on the market first played a role in Ethicon's executives putting political pressure on its employees to get the Type of the document of the product on the market from a product launched?  Page 183  A. They should not be documents, and that they are opinion based on your review of the document of the product on the market first played a role in Ethicon's executives putting political pressure on its employees to get the Type of the document of the product on the market first played a role in Ethicon's executives putting political pressure on its employees to get the Type of the document of the product on the market first played a role in Ethicon's executives putting political pressure on its employees to get the Type of the document of the product on the market the product on the market	1	Q. Do you have an opinion whether or not	1	pressure on their employees in order to rush a
4 what is being described here in this document? 5 MR. SNELL: Object. 6 BY THE WITNESS: 7 A. Yes. 8 BY MR. THORNBURGH: 9 Q. What's that opinion? 10 A. That they do deserve better 11 consideration than just top executives at Ethicon 12 discussing that there are more likely than not big 13 problems associated with the device design, 14 characteristics that are unreasonably unsafe or 15 make it unreasonably ineffective, and that they 16 are - those are being ignored and a product is 17 being rushed to market. 18 Q. Did Bithicon ever fix any of the problems 19 with their design validation? 20 MR. SNELL: Objection. 21 BY THE WITNESS: 22 A. No, they did not. 23 BY MR. THORNBURGH: 24 Q. Based on your review of the documents, 25 Page 183 2 A. No, they did not. 26 A. No, they did not. 27 Page 183 28 Page 184 29 A. In February 2000 until September of 2006? 29 A. No they did not. 30 Giscussion about design characteristics that are discussion about design characteristics that are discussion about design characteristics that made 11 it unreasonably unsafe or unreasonably ineffective. 12 Those characteristics were not identified. 13 It was found to be unreasonably unsafe or unreasonably ineffective. 14 A. No, they did not. 15 Q. And why is that ait important? Is that 16 important to your opinion? 17 A. Yes, it is. 18 Q. Why is that? 19 Q. And why is that important? Is that 19 Giscussion about design characteristics that made 11 it unreasonably unsafe or unreasonably ineffective. 12 Those characteristics were not identified. 13 The product was placed on the market. 14 It was found to be unreasonably unsafe or unreasonably ineffective in treating stress urinary 15 incontinence and led to complications in women 16 which could have and should have been identified 18 during this time period and either fixed prior to 19 quanched or launch either stopped completely and the product never put on the market or at least 20 Q. Do you have an opinion whether or not 21 diddessed and identified. 22 Q. Do you have an opinion whether or not	2	women deserve better conduct from medical device	2	product through to get it launched?
5 MR. SNELL: Object. 6 BYTHE WITNESS: 7 A. Yes. 8 BYMR. THORNBURGH: 9 Q. What's that opinion? 10 A. That they do deserve better 11 consideration than just top executives at Ethicon 12 discussing that there are more likely than not big 13 problems associated with the device design, 14 characteristics that are unreasonably unsafe or make it unreasonably ineffective, and that they 16 are – those are being ignored and a product is 17 being rushed to market. 18 Q. Did Ethicon ever fix any of the problems 19 with their design validation? 19 MR. SNELL: Objection. 10 BY MR. THORNBURGH: 20 A. No, they did not. 21 BY MR. THORNBURGH: 22 A. No, they did not. 23 BY MR. THORNBURGH: 24 Q. Based on your review of the documents, 3 February 2006 until September of 2006? 4 A. No, they did not. 5 Q. And why is that important? Is that 6 important to your opinion? 7 A. Yes, it is. 8 Q. Why is that? 9 A. In February 9, 2006, there were – was 10 discussion about design characteristics that made 11 it urreasonably unsafe or unreasonably ineffective. 12 Those characteristics were not identified. 13 It was found to be unreasonably ineffective in treating stress urinary 14 incontinence and led to complications in women 15 which could have and should have been identified 16 during this time period and either fixed prior to 18 product never put on the market or at least 18 quirned the product never thange its design before they 19 Launched the product on the market from 20 G. Do you know bretter or not the documents. 21 the stream of the product of the market from 22 product launched? 23 BY MR. THORNBURGH: 24 product launched? 25 product launched? 26 product launched? 27 product launched? 28 product launched? 29 product launched? 30 product launched? 31 product launched? 32 product launched? 33 product launched? 34 product launched? 35 product launched? 36 product launched? 37 product launched? 38 product launched? 39 product launched? 40 product launched? 51 product launched? 52 product launched? 53 product launched? 54 product launched? 5	3	companies like Ethicon and Johnson & Johnson than	3	MR. SNELL: Objection.
6 BYTHE WITNESS: 7 A. Yes. 8 BYMR, THORNBURGH: 9 Q. What's that opinion? 10 A. That they do deserve better 11 consideration than just top executives at Ethicon 12 discussing that there are more likely than not big 13 problems associated with the device design, 14 characteristics that are unreasonably unsafe or 15 make it unreasonably ineffective, and that they 16 are – those are being ignored and a product is 17 being rushed to market. 18 Q. Did Ethicon ever fix any of the problems 19 with their design validation? 10 MR. SNELL: Objection. 11 BY THE WITNESS: 12 A. No, they did not. 12 BY MR. THORNBURGH: 13 BY MR. THORNBURGH: 14 Was a sound to be unreasonably ineffective in treating stress urinary 15 being rushed to market. 16 Q. Did Ethicon ever fix any of the problems 17 BY MR. THORNBURGH: 18 With their design validation? 19 With their design validation? 20 MR. SNELL: Objection. 21 BY THE WITNESS: 22 A. No, they did not. 23 BY MR. THORNBURGH: 24 Q. Based on your review of the documents, 25 BY MR. THORNBURGH: 26 Q. Based on your review of the documents, 27 Page 183 28 Page 183 29 A. No, they did not. 29 BY MR. THORNBURGH: 20 Launched the product on the market from 21 Gid Ethicon ever change its design before they 22 launched the product on the market from 23 February 2006 until September of 2006? 24 A. No, they did not. 25 Q. And why is that important? Is that important to your opinion? 26 A. Yes, it is. 27 Page 183 28 PAGE THORNBURGH: 28 Page 183 3 Page 16 4 Page 183 4 Page 183 4 Page 184 5 Page 185 6 D. And what's that opinion? 6 A. Yes, it is. 7 A. Yes, it is. 8 Q. Why is that? 9 A. In February 9, 2006, there were – was of discussion about design characteristics that made it unreasonably unsafe or unreasonably ineffective in treating stress urinary in the incontence and led to complications in women which could have and should have been identified. 16 incontinence and led to complications in women which could have and should have been identified. 17 Page 184 18 With the design have been identified. 18 during	4	what is being described here in this document?	4	BY THE WITNESS:
8 BY MR. THORNBURGH: 9 Q. What's that opinion? 10 A. That they do deserve better 11 consideration than just top executives at Ethicon 12 discussing that there are more likely than not big 13 problems associated with the device design, 14 characteristics that are unreasonably unsafe or 15 make it unreasonably ineffective, and that they 16 are – those are being ignored and a product is 17 being rushed to market. 18 Q. Did Ethicon ever fix any of the problems 19 with their design validation? 20 MR. SNELL: Objection. 21 BY THE WITNESS: 21 BY THE WITNESS: 22 A. No, they did not. 23 BY MR. THORNBURGH: 24 Q. Based on your review of the documents, 25 BY MR. THORNBURGH: 26 did Ethicon ever change its design before they 27 launched the product on the market from 38 February 2006 until September of 2006? 4 A. No, they did not. 5 Q. And why is that important? Is that important to your opinion? 6 A. Yes, it is. 8 Q. Why is that? 9 A. In February 9. 2006, there were – was 10 discussion about design characteristics that made 11 it urreasonably unsafe or unreasonably imeffective, in reading stress urinary 16 incontinence and led to complications in women 17 which could have and pinion whether or not to go boug troview of the medical – review of the hedical – review of the h	5	MR. SNELL: Object.	5	A. Yes, I have an opinion.
B BY MR. THORNBURGH: 9 Q. What's that opinion? 10 A. That they do deserve better 11 consideration than just top executives at Ethicon 12 discussing that there are more likely than not big 13 problems associated with the device design, 14 characteristics that are unreasonably unsafe or 15 make it unreasonably ineffective, and that they 16 are - those are being ignored and a product is 17 being rushed to market. 18 Q. Did Ethicon ever fix any of the problems 19 with their design validation? 20 MR. SNELL: Objection. 21 BY THE WITNESS: 22 A. No, they did not. 22 A. No, they did not. 23 BY MR. THORNBURGH: 24 Q. Based on your review of the documents, 25 BY MR. THORNBURGH: 26 A. No, they did not. 27 Page 183 28 Idd Ethicon ever change its design before they 29 launched the product on the market from 30 February 2006 until September of 2006? 41 A. No, they did not. 42 Q. And why is that important? Is that 43 important to your opinion? 44 A. No, they did not. 45 Q. And why is that important? Is that 46 important to your opinion? 4 A. Yes, it is. 4 Q. Why is that 4 It was found to be unreasonably ineffective in treating stress urinary 16 incontinence and led to complications in women 17 which could have and should have been identified 18 during this time period and either fixed prior to 19 launch or launch either stopped completely and the 20 product never put on the market or at least 21 addressed and identified. 22 Q. Do you have an opinion whether or not 24 mR. SNELL: Objection. 25 Do you know whether or not that we had reviewed previously, whethe	6	BY THE WITNESS:	6	BY MR. THORNBURGH:
9 Q. Do you have an opinion based on your review of the medical review of Ethicon's internal documents the purpose for putting political pressure on employees in order to get the TVT-Secur launched?  13 make it unreasonably ineffective, and that they are those are being ignored and a product is being rushed to market.  16 are those are being ignored and a product is being rushed to market.  17 being rushed to market.  18 Q. Did Ethicon ever fix any of the problems with their design validation?  20 MR. SNELL: Objection.  21 BY THE WITNESS:  22 A. No, they did not.  23 BY MR. THORNBURGH:  24 Q. Based on your review of the documents,  25 Page 183  26 did Ethicon ever change its design before they launched the product on the market from 2 launched the product on the market from 2 launched the product on the market from 3 February 2006 until September of 2006?  3 February 2006 until September of 2006?  4 A. No, they did not.  5 Q. And why is that important? Is that important to your opinion?  5 Q. Why is that?  8 Q. Why is that?  9 A. In February 9, 2006, there were was discussion about design characteristics that made it it urreasonably unsafe or unreasonably ineffective in treating stress urinary incontinence and led to complications in women which could have and should have been identified uring this time period and either fixed prior to 18 launch or launch cither stopped completely and the product necent product necent continued and identified.  20 Do you have an opinion whether or not 2 microal political pressure on employees in order to get the TVT-Secur launched?  A. Can you repeat the question again.  BY THE WITNESS:  A. Can you repart the question again.  BY THE WITNESS:  A. Can you repart the question again.  BY MR. THORNBURGH:  Do you know whether or not the document that we had reviewed previously, whether or not the rect of get a mini-sling to the market first played a role in Ethicon's executive sputting political pressure on its employees to get the TVT-Secur launched?  MR. SNELL: Objectio	7	A. Yes.	7	Q. What's that opinion?
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22 Q. Do you have an opinion whether or not 22 opinions?		-		
43 Hedical device companies like Ethicon and   43 MK. SNELL: Object.				-
24 Johnson & Johnson should ever put immense political 24 BY THE WITNESS:	∠4	Jonnson & Jonnson snould ever put immense political	24	BY THE WITNESS:

	Page 186		Page 188
1	A. It is important that any characteristics	1	Based on Exhibit P0542, do you have an
2	of a device that are found to be unreasonably	2	opinion whether or not Ethicon knew or should have
3	unsafe or make a device unreasonably ineffective	3	known that it would be inappropriate for Ethicon to
4	are described in detail and not spun in a way that	4	rely on data from its other TVT products?
5	makes it more palatable.	5	MR. SNELL: Objection.
6	Those characteristics should be	6	BY THE WITNESS:
7	described and fixed and either the device not	7	A. Yes, I do have an opinion.
8	launched or those characteristics fixed before a	8	BY MR. THORNBURGH:
9	product is launched.	9	Q. And what is that opinion?
10	BY MR. THORNBURGH:	10	A. Yes, it would this communication
11	Q. Okay. And what is is there anything	11	between key Ethicon employees does show an
12	else relevant to that last exhibit we were looking	12	understanding that the TVT-Secur is a new product
13	at to your opinions?	13	and therefore the data from their other full-length
14	A. No.	14	products would not be applicable to the the
15	Q. What's the next exhibit that you want to	15	short, stiff, rigid mesh that had never been used
16	discuss with the jury?	16	before, the fleece tips that had never been used
17	A. P0542.	17	for, the sharp arrowhead introducer that had never
18	Q. And can you explain to the ladies and	18	been used before.
19	gentlemen of the jury what P0542 is?	19	Q. Let me just make sure I understand
20	A. It is an e-mail from Allison London	20	really quick. If we look at P0542.
21	Brown, who is the worldwide launch coordinator for	21	MR. THORNBURGH: Tom, if you could blow up the
22	the TVT-Secur, and Dan Smith, the lead engineer and	22	section under "TVT-Secur."
23	co-patent holder for the TVT-Secur, discussing the	23	BY MR. THORNBURGH:
24	TVT-Secur device as a new product or technique and	24	Q. It says, "TVT-Secur is a new
	1		, , , , , , , , , , , , , , , , , , ,
	D 10E		
	Page 187		Page 189
1	has little relationship with the data that had been	1	Page 189 product/technique and therefore there is little
1 2		1 2	
	has little relationship with the data that had been		product/technique and therefore there is little
2	has little relationship with the data that had been obtained from the full-length retropubic sling that	2	product/technique and therefore there is little relationship to the TVT 7-year data."
2 3	has little relationship with the data that had been obtained from the full-length retropubic sling that I discussed earlier in my testimony.	2 3	product/technique and therefore there is little relationship to the TVT 7-year data."  Did I read that correctly?
2 3 4	has little relationship with the data that had been obtained from the full-length retropubic sling that I discussed earlier in my testimony.  Q. How, if at all, is Exhibit P0542	2 3 4	product/technique and therefore there is little relationship to the TVT 7-year data."  Did I read that correctly?  MR. SNELL: Objection; leading.
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	Page 190		Page 192
1	correct?	1	reliance list.
2	A. Correct.	2	MR. SNELL: That's fine. Then I'll say I'm
3	Q. So, these aren't your words, right?	3	wrong. We are trying to run word searches on this
4	MR. SNELL: Objection.	4	large reliance list and number searches and it's
5	BY MR. THORNBURGH:	5	just not showing up.
6	Q. Are these your words?	6	MR. THORNBURGH: Gotcha.
7	MR. SNELL: Same objection.	7	BY MR. THORNBURGH:
8	BY MR. THORNBURGH:	8	Q. Sorry, Doctor. What's the next exhibit
9	Q. Let me ask again.	9	that you'd like to discuss with the ladies and
10	Are the words that we see on page the	10	gentlemen of the jury?
11	first page of P0542, are those your words?	11	A. P0716.
12	MR. SNELL: Objection.	12	Q. And what's the date of this document?
13	BY THE WITNESS:	13	A. This is an e-mail string from June 20,
14	A. No. This comes from an internal Ethicon	14	2006.
15	document.	15	O. Is this before or after the TVT-Secur
16	BY MR. THORNBURGH:	16	product was launched?
17	Q. And are those words that you agree with?	17	A. It is approximately three months prior
18	A. Yes.	18	to launch.
19	Q. And how many years were those written,	19	Q. And do you strike that.
20	those words written by Ethicon's employees before	20	How does Exhibit P0716 support, if at
21	you were ever involved in this litigation?	21	all, your opinions in this case?
22	A. This is from 2006.	22	A. This supports my opinion that the
23	Q. Are the words in any of these documents	23	TVT-Secur device should have been studied in
24	that we're looking at, are those your words?	24	randomized controlled trials before launch and
	Page 191		Page 193
1	MR. SNELL: Objection.	1	doing so did not allow doctors and scientists to
2	BY THE WITNESS:	2	know the device characteristics that made it
3	A. No, these are from internal Ethicon	3	unreasonably unsafe and also unreasonably
4	documents.	4	ineffective.
5	BY MR. THORNBURGH:	5	<ul> <li>Q. What part of this document supports your</li> </ul>
6	Q. And do you agree with some of the words	~	
		6	opinion that Ethicon should have studied in
7	and opinions that are being expressed in the		opinion that Ethicon should have studied in randomized controlled trials the TVT-Secur before
7 8		6	opinion that Ethicon should have studied in
_	and opinions that are being expressed in the	6 7	opinion that Ethicon should have studied in randomized controlled trials the TVT-Secur before
8	and opinions that are being expressed in the documents that we're looking at?	6 7 8	opinion that Ethicon should have studied in randomized controlled trials the TVT-Secur before they launched it?  A. Well, this e-mail describes that two very well-known doctors and Key Opinion Leaders,
8 9	and opinions that are being expressed in the documents that we're looking at?  MR. SNELL: Same objection.	6 7 8 9	opinion that Ethicon should have studied in randomized controlled trials the TVT-Secur before they launched it?  A. Well, this e-mail describes that two very well-known doctors and Key Opinion Leaders, Dr. Nilsson and Dr. Artibani, expressed their
8 9 10	and opinions that are being expressed in the documents that we're looking at?  MR. SNELL: Same objection.  BY THE WITNESS:	6 7 8 9 10	opinion that Ethicon should have studied in randomized controlled trials the TVT-Secur before they launched it?  A. Well, this e-mail describes that two very well-known doctors and Key Opinion Leaders, Dr. Nilsson and Dr. Artibani, expressed their worries about Ethicon launching TVT-Secur with no
8 9 10 11	and opinions that are being expressed in the documents that we're looking at?  MR. SNELL: Same objection.  BY THE WITNESS:  A. Yes.	6 7 8 9 10 11	opinion that Ethicon should have studied in randomized controlled trials the TVT-Secur before they launched it?  A. Well, this e-mail describes that two very well-known doctors and Key Opinion Leaders, Dr. Nilsson and Dr. Artibani, expressed their
8 9 10 11 12	and opinions that are being expressed in the documents that we're looking at?  MR. SNELL: Same objection.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:	6 7 8 9 10 11 12	opinion that Ethicon should have studied in randomized controlled trials the TVT-Secur before they launched it?  A. Well, this e-mail describes that two very well-known doctors and Key Opinion Leaders, Dr. Nilsson and Dr. Artibani, expressed their worries about Ethicon launching TVT-Secur with no clinical data other than 50 patients with five weeks of follow-up.
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8 9 10 11 12 13 14 15 16	and opinions that are being expressed in the documents that we're looking at?  MR. SNELL: Same objection.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:  Q. What's the next exhibit you'd like to discuss with the ladies and gentlemen of the jury?  A. P0716.  MR. SNELL: Just for the record I didn't see P0279 on his exhibit list. We have been checking.	6 7 8 9 10 11 12 13 14 15 16	opinion that Ethicon should have studied in randomized controlled trials the TVT-Secur before they launched it?  A. Well, this e-mail describes that two very well-known doctors and Key Opinion Leaders, Dr. Nilsson and Dr. Artibani, expressed their worries about Ethicon launching TVT-Secur with no clinical data other than 50 patients with five weeks of follow-up.  Q. And let me stop you right there for a moment.  Who is Professor Nilsson?
8 9 10 11 12 13 14 15 16 17 18	and opinions that are being expressed in the documents that we're looking at?  MR. SNELL: Same objection.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:  Q. What's the next exhibit you'd like to discuss with the ladies and gentlemen of the jury?  A. P0716.  MR. SNELL: Just for the record I didn't see P0279 on his exhibit list. We have been checking. So, I move to strike all testimony about it.	6 7 8 9 10 11 12 13 14 15 16 17	opinion that Ethicon should have studied in randomized controlled trials the TVT-Secur before they launched it?  A. Well, this e-mail describes that two very well-known doctors and Key Opinion Leaders, Dr. Nilsson and Dr. Artibani, expressed their worries about Ethicon launching TVT-Secur with no clinical data other than 50 patients with five weeks of follow-up.  Q. And let me stop you right there for a moment.  Who is Professor Nilsson?  A. Dr. Nilsson is one of the co-inventors
8 9 10 11 12 13 14 15 16 17 18	and opinions that are being expressed in the documents that we're looking at?  MR. SNELL: Same objection.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:  Q. What's the next exhibit you'd like to discuss with the ladies and gentlemen of the jury?  A. P0716.  MR. SNELL: Just for the record I didn't see P0279 on his exhibit list. We have been checking.  So, I move to strike all testimony about it.  MR. THORNBURGH: And just for the record it's	6 7 8 9 10 11 12 13 14 15 16 17 18	opinion that Ethicon should have studied in randomized controlled trials the TVT-Secur before they launched it?  A. Well, this e-mail describes that two very well-known doctors and Key Opinion Leaders, Dr. Nilsson and Dr. Artibani, expressed their worries about Ethicon launching TVT-Secur with no clinical data other than 50 patients with five weeks of follow-up.  Q. And let me stop you right there for a moment.  Who is Professor Nilsson?  A. Dr. Nilsson is one of the co-inventors of the TVT Retropubic, probably has the most
8 9 10 11 12 13 14 15 16 17 18 19 20	and opinions that are being expressed in the documents that we're looking at?  MR. SNELL: Same objection. BY THE WITNESS:  A. Yes. BY MR. THORNBURGH: Q. What's the next exhibit you'd like to discuss with the ladies and gentlemen of the jury? A. P0716.  MR. SNELL: Just for the record I didn't see P0279 on his exhibit list. We have been checking. So, I move to strike all testimony about it.  MR. THORNBURGH: And just for the record it's on there. We can address this later on.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	opinion that Ethicon should have studied in randomized controlled trials the TVT-Secur before they launched it?  A. Well, this e-mail describes that two very well-known doctors and Key Opinion Leaders, Dr. Nilsson and Dr. Artibani, expressed their worries about Ethicon launching TVT-Secur with no clinical data other than 50 patients with five weeks of follow-up.  Q. And let me stop you right there for a moment.  Who is Professor Nilsson?  A. Dr. Nilsson is one of the co-inventors of the TVT Retropubic, probably has the most experience with midurethral slings and is a Key
8 9 10 11 12 13 14 15 16 17 18 19 20 21	and opinions that are being expressed in the documents that we're looking at?  MR. SNELL: Same objection.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:  Q. What's the next exhibit you'd like to discuss with the ladies and gentlemen of the jury?  A. P0716.  MR. SNELL: Just for the record I didn't see P0279 on his exhibit list. We have been checking.  So, I move to strike all testimony about it.  MR. THORNBURGH: And just for the record it's on there. We can address this later on.  MR. SNELL: Oh, yeah.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	opinion that Ethicon should have studied in randomized controlled trials the TVT-Secur before they launched it?  A. Well, this e-mail describes that two very well-known doctors and Key Opinion Leaders, Dr. Nilsson and Dr. Artibani, expressed their worries about Ethicon launching TVT-Secur with no clinical data other than 50 patients with five weeks of follow-up.  Q. And let me stop you right there for a moment.  Who is Professor Nilsson?  A. Dr. Nilsson is one of the co-inventors of the TVT Retropubic, probably has the most experience with midurethral slings and is a Key Opinion Leader for Ethicon.

49 (Pages 190 to 193)

	Page 194		Page 196
1	MR. SNELL: Objection.	1	A. I agree.
2	MR. THORNBURGH: Sorry. Strike that. Let me	2	BY MR. THORNBURGH:
3	strike that. Withdraw that.	3	Q. And are those your words?
4	BY MR. THORNBURGH:	4	A. No. Those are the concerns expressed by
5	Q. Who was Dr. Nilsson?	5	Dr. Nilsson and Dr. Artibani.
6	A. Dr. Nilsson was a contemporary with the	6	MR. THORNBURGH: And if we go further down on
7	inventor of the TVT Retropubic. From my	7	Bates number 851, Tom, if you can blow up where it
8	understanding, he was with Dr. Ulmsten during the	8	begins with "I'm a bit concerned."
9	early the earliest clinical trials with the	9	BY MR. THORNBURGH:
10	TVT Retropubic.	10	Q. Harel Gadot. Who is Harel Gadot?
11	Q. And did he publish was he a	11	A. He is the European marketing manager.
12	co-publisher of data concerning the TVT Retropubic,	12	O. And for Ethicon?
13		13	A. Yes.
14	the first generation TVT device?  A. Yes.	14	
15	Q. And who is Dr. Professor Artibani?	15	concerned that by canceling the RCT we will hurt
16	A. Dr. Artibani is a pelvic surgeon from	16	our image in their eyes, especially after we've
17	Italy who is also a Key Opinion Leader for Ethicon,	17	communicated this to them and worked with them to
18	very well-known pelvic surgeon.	18	resolve any concerns they had associating with
19	Q. Both of them are both Professor	19	TVT-Secur. I believe the success of the launch of
20	Nilsson and Professor Artibani licensed medical	20	TVT-Secur across EMEA" do you understand what
21	doctors?	21	EMEA stands for?
22	A. Yes.	22	A. Yes. It's Europe Middle East and
23	Q. Or were they when they were alive? Were	23	Africa.
24	they medical doctors, based on your understanding?	24	Q. "And probably other parts WW." Is that
	Page 195		Page 197
1			
	A. Yes.	1	worldwide?
2	<ul><li>A. Yes.</li><li>Q. And as we see on page 2 of this</li></ul>	1 2	worldwide? A. Yes.
2	Q. And as we see on page 2 of this Exhibit 716, Bates number ending in 851, midway	2	A. Yes.
2 3	Q. And as we see on page 2 of this	2 3	<ul><li>A. Yes.</li><li>Q. "Will depend heavily on those two Key</li><li>Opinion Leaders and their willingness to assist us</li></ul>
2 3 4	Q. And as we see on page 2 of this Exhibit 716, Bates number ending in 851, midway through this page it says, "Regarding the proposed	2 3 4	A. Yes. Q. "Will depend heavily on those two Key Opinion Leaders and their willingness to assist us with our future communication plans. Therefore I
2 3 4 5	Q. And as we see on page 2 of this Exhibit 716, Bates number ending in 851, midway through this page it says, "Regarding the proposed RCT," and that's randomized controlled trial, is	2 3 4 5	A. Yes. Q. "Will depend heavily on those two Key Opinion Leaders and their willingness to assist us with our future communication plans. Therefore I would strongly recommend to find a way not to
2 3 4 5 6	Q. And as we see on page 2 of this Exhibit 716, Bates number ending in 851, midway through this page it says, "Regarding the proposed RCT," and that's randomized controlled trial, is that correct?  A. Yes.	2 3 4 5 6	A. Yes. Q. "Will depend heavily on those two Key Opinion Leaders and their willingness to assist us with our future communication plans. Therefore I
2 3 4 5 6 7	Q. And as we see on page 2 of this Exhibit 716, Bates number ending in 851, midway through this page it says, "Regarding the proposed RCT," and that's randomized controlled trial, is that correct?	2 3 4 5 6 7	A. Yes. Q. "Will depend heavily on those two Key Opinion Leaders and their willingness to assist us with our future communication plans. Therefore I would strongly recommend to find a way not to cancel completely the proposed RCT."
2 3 4 5 6 7 8	Q. And as we see on page 2 of this Exhibit 716, Bates number ending in 851, midway through this page it says, "Regarding the proposed RCT," and that's randomized controlled trial, is that correct?  A. Yes. Q. "Both Professor Nilsson and Professor	2 3 4 5 6 7 8	A. Yes. Q. "Will depend heavily on those two Key Opinion Leaders and their willingness to assist us with our future communication plans. Therefore I would strongly recommend to find a way not to cancel completely the proposed RCT."  Did I read that correctly?
2 3 4 5 6 7 8	Q. And as we see on page 2 of this Exhibit 716, Bates number ending in 851, midway through this page it says, "Regarding the proposed RCT," and that's randomized controlled trial, is that correct?  A. Yes. Q. "Both Professor Nilsson and Professor Artibani expressed their worries about us launching	2 3 4 5 6 7 8	A. Yes. Q. "Will depend heavily on those two Key Opinion Leaders and their willingness to assist us with our future communication plans. Therefore I would strongly recommend to find a way not to cancel completely the proposed RCT." Did I read that correctly? MR. SNELL: Objection; leading.
2 3 4 5 6 7 8 9	Q. And as we see on page 2 of this Exhibit 716, Bates number ending in 851, midway through this page it says, "Regarding the proposed RCT," and that's randomized controlled trial, is that correct?  A. Yes. Q. "Both Professor Nilsson and Professor Artibani expressed their worries about us launching TVT-Secur with no clinical data (other than the 50	2 3 4 5 6 7 8 9	A. Yes. Q. "Will depend heavily on those two Key Opinion Leaders and their willingness to assist us with our future communication plans. Therefore I would strongly recommend to find a way not to cancel completely the proposed RCT." Did I read that correctly? MR. SNELL: Objection; leading. BY THE WITNESS:
2 3 4 5 6 7 8 9 10 11	Q. And as we see on page 2 of this Exhibit 716, Bates number ending in 851, midway through this page it says, "Regarding the proposed RCT," and that's randomized controlled trial, is that correct?  A. Yes. Q. "Both Professor Nilsson and Professor Artibani expressed their worries about us launching TVT-Secur with no clinical data (other than the 50 patients, 5 week follow-up)."	2 3 4 5 6 7 8 9 10	A. Yes. Q. "Will depend heavily on those two Key Opinion Leaders and their willingness to assist us with our future communication plans. Therefore I would strongly recommend to find a way not to cancel completely the proposed RCT." Did I read that correctly? MR. SNELL: Objection; leading. BY THE WITNESS: A. Yes.
2 3 4 5 6 7 8 9 10 11 12	Q. And as we see on page 2 of this Exhibit 716, Bates number ending in 851, midway through this page it says, "Regarding the proposed RCT," and that's randomized controlled trial, is that correct?  A. Yes. Q. "Both Professor Nilsson and Professor Artibani expressed their worries about us launching TVT-Secur with no clinical data (other than the 50 patients, 5 week follow-up)."  Did I read that correctly?	2 3 4 5 6 7 8 9 10 11 12	A. Yes. Q. "Will depend heavily on those two Key Opinion Leaders and their willingness to assist us with our future communication plans. Therefore I would strongly recommend to find a way not to cancel completely the proposed RCT." Did I read that correctly? MR. SNELL: Objection; leading. BY THE WITNESS: A. Yes. BY MR. THORNBURGH:
2 3 4 5 6 7 8 9 10 11 12 13	Q. And as we see on page 2 of this Exhibit 716, Bates number ending in 851, midway through this page it says, "Regarding the proposed RCT," and that's randomized controlled trial, is that correct?  A. Yes. Q. "Both Professor Nilsson and Professor Artibani expressed their worries about us launching TVT-Secur with no clinical data (other than the 50 patients, 5 week follow-up)."  Did I read that correctly? MR. SNELL: Object; leading.	2 3 4 5 6 7 8 9 10 11 12 13	A. Yes. Q. "Will depend heavily on those two Key Opinion Leaders and their willingness to assist us with our future communication plans. Therefore I would strongly recommend to find a way not to cancel completely the proposed RCT." Did I read that correctly? MR. SNELL: Objection; leading. BY THE WITNESS: A. Yes. BY MR. THORNBURGH: Q. And how, if at all, does do those
2 3 4 5 6 7 8 9 10 11 12 13 14	Q. And as we see on page 2 of this Exhibit 716, Bates number ending in 851, midway through this page it says, "Regarding the proposed RCT," and that's randomized controlled trial, is that correct?  A. Yes. Q. "Both Professor Nilsson and Professor Artibani expressed their worries about us launching TVT-Secur with no clinical data (other than the 50 patients, 5 week follow-up)."  Did I read that correctly? MR. SNELL: Object; leading. BY THE WITNESS:	2 3 4 5 6 7 8 9 10 11 12 13 14	A. Yes. Q. "Will depend heavily on those two Key Opinion Leaders and their willingness to assist us with our future communication plans. Therefore I would strongly recommend to find a way not to cancel completely the proposed RCT." Did I read that correctly? MR. SNELL: Objection; leading. BY THE WITNESS: A. Yes. BY MR. THORNBURGH: Q. And how, if at all, does do those statements from Dr. Harel Gadot support your
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. And as we see on page 2 of this Exhibit 716, Bates number ending in 851, midway through this page it says, "Regarding the proposed RCT," and that's randomized controlled trial, is that correct?  A. Yes. Q. "Both Professor Nilsson and Professor Artibani expressed their worries about us launching TVT-Secur with no clinical data (other than the 50 patients, 5 week follow-up)."  Did I read that correctly? MR. SNELL: Object; leading. BY THE WITNESS: A. Yes. BY MR. THORNBURGH:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. Yes. Q. "Will depend heavily on those two Key Opinion Leaders and their willingness to assist us with our future communication plans. Therefore I would strongly recommend to find a way not to cancel completely the proposed RCT." Did I read that correctly? MR. SNELL: Objection; leading. BY THE WITNESS: A. Yes. BY MR. THORNBURGH: Q. And how, if at all, does do those statements from Dr. Harel Gadot support your opinion? A. They support my opinion that randomized
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. And as we see on page 2 of this Exhibit 716, Bates number ending in 851, midway through this page it says, "Regarding the proposed RCT," and that's randomized controlled trial, is that correct?  A. Yes. Q. "Both Professor Nilsson and Professor Artibani expressed their worries about us launching TVT-Secur with no clinical data (other than the 50 patients, 5 week follow-up)."  Did I read that correctly? MR. SNELL: Object; leading. BY THE WITNESS: A. Yes. BY MR. THORNBURGH: Q. And do you agree or disagree with the concerns that are being expressed by Professor	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Yes. Q. "Will depend heavily on those two Key Opinion Leaders and their willingness to assist us with our future communication plans. Therefore I would strongly recommend to find a way not to cancel completely the proposed RCT." Did I read that correctly? MR. SNELL: Objection; leading. BY THE WITNESS: A. Yes. BY MR. THORNBURGH: Q. And how, if at all, does do those statements from Dr. Harel Gadot support your opinion? A. They support my opinion that randomized controlled trials should have been done prior to
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. And as we see on page 2 of this Exhibit 716, Bates number ending in 851, midway through this page it says, "Regarding the proposed RCT," and that's randomized controlled trial, is that correct?  A. Yes. Q. "Both Professor Nilsson and Professor Artibani expressed their worries about us launching TVT-Secur with no clinical data (other than the 50 patients, 5 week follow-up)."  Did I read that correctly? MR. SNELL: Object; leading. BY THE WITNESS: A. Yes. BY MR. THORNBURGH: Q. And do you agree or disagree with the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Yes. Q. "Will depend heavily on those two Key Opinion Leaders and their willingness to assist us with our future communication plans. Therefore I would strongly recommend to find a way not to cancel completely the proposed RCT." Did I read that correctly? MR. SNELL: Objection; leading. BY THE WITNESS: A. Yes. BY MR. THORNBURGH: Q. And how, if at all, does do those statements from Dr. Harel Gadot support your opinion? A. They support my opinion that randomized controlled trials should have been done prior to launch of the TVT-Secur so that the design
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. And as we see on page 2 of this Exhibit 716, Bates number ending in 851, midway through this page it says, "Regarding the proposed RCT," and that's randomized controlled trial, is that correct?  A. Yes. Q. "Both Professor Nilsson and Professor Artibani expressed their worries about us launching TVT-Secur with no clinical data (other than the 50 patients, 5 week follow-up)." Did I read that correctly? MR. SNELL: Object; leading. BY THE WITNESS: A. Yes. BY MR. THORNBURGH: Q. And do you agree or disagree with the concerns that are being expressed by Professor Nilsson and Professor Artibani concerning releasing	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. Yes. Q. "Will depend heavily on those two Key Opinion Leaders and their willingness to assist us with our future communication plans. Therefore I would strongly recommend to find a way not to cancel completely the proposed RCT." Did I read that correctly? MR. SNELL: Objection; leading. BY THE WITNESS: A. Yes. BY MR. THORNBURGH: Q. And how, if at all, does do those statements from Dr. Harel Gadot support your opinion? A. They support my opinion that randomized controlled trials should have been done prior to launch of the TVT-Secur so that the design characteristics that made it unreasonably unsafe
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q. And as we see on page 2 of this Exhibit 716, Bates number ending in 851, midway through this page it says, "Regarding the proposed RCT," and that's randomized controlled trial, is that correct?  A. Yes. Q. "Both Professor Nilsson and Professor Artibani expressed their worries about us launching TVT-Secur with no clinical data (other than the 50 patients, 5 week follow-up)."  Did I read that correctly? MR. SNELL: Object; leading. BY THE WITNESS: A. Yes. BY MR. THORNBURGH: Q. And do you agree or disagree with the concerns that are being expressed by Professor Nilsson and Professor Artibani concerning releasing the TVT-Secur with no randomized controlled trial or clinical data other than the 50 patient,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. Yes. Q. "Will depend heavily on those two Key Opinion Leaders and their willingness to assist us with our future communication plans. Therefore I would strongly recommend to find a way not to cancel completely the proposed RCT." Did I read that correctly? MR. SNELL: Objection; leading. BY THE WITNESS: A. Yes. BY MR. THORNBURGH: Q. And how, if at all, does do those statements from Dr. Harel Gadot support your opinion? A. They support my opinion that randomized controlled trials should have been done prior to launch of the TVT-Secur so that the design characteristics that made it unreasonably unsafe and unreasonably ineffective would have been known prior to launch and either the product not launched
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. And as we see on page 2 of this Exhibit 716, Bates number ending in 851, midway through this page it says, "Regarding the proposed RCT," and that's randomized controlled trial, is that correct?  A. Yes. Q. "Both Professor Nilsson and Professor Artibani expressed their worries about us launching TVT-Secur with no clinical data (other than the 50 patients, 5 week follow-up)."  Did I read that correctly? MR. SNELL: Object; leading. BY THE WITNESS: A. Yes. BY MR. THORNBURGH: Q. And do you agree or disagree with the concerns that are being expressed by Professor Nilsson and Professor Artibani concerning releasing the TVT-Secur with no randomized controlled trial	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. Q. "Will depend heavily on those two Key Opinion Leaders and their willingness to assist us with our future communication plans. Therefore I would strongly recommend to find a way not to cancel completely the proposed RCT." Did I read that correctly? MR. SNELL: Objection; leading. BY THE WITNESS: A. Yes. BY MR. THORNBURGH: Q. And how, if at all, does do those statements from Dr. Harel Gadot support your opinion? A. They support my opinion that randomized controlled trials should have been done prior to launch of the TVT-Secur so that the design characteristics that made it unreasonably unsafe and unreasonably ineffective would have been known
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And as we see on page 2 of this Exhibit 716, Bates number ending in 851, midway through this page it says, "Regarding the proposed RCT," and that's randomized controlled trial, is that correct?  A. Yes. Q. "Both Professor Nilsson and Professor Artibani expressed their worries about us launching TVT-Secur with no clinical data (other than the 50 patients, 5 week follow-up)."  Did I read that correctly? MR. SNELL: Object; leading. BY THE WITNESS: A. Yes. BY MR. THORNBURGH: Q. And do you agree or disagree with the concerns that are being expressed by Professor Nilsson and Professor Artibani concerning releasing the TVT-Secur with no randomized controlled trial or clinical data other than the 50 patient, five-week follow-up study?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. Q. "Will depend heavily on those two Key Opinion Leaders and their willingness to assist us with our future communication plans. Therefore I would strongly recommend to find a way not to cancel completely the proposed RCT." Did I read that correctly? MR. SNELL: Objection; leading. BY THE WITNESS: A. Yes. BY MR. THORNBURGH: Q. And how, if at all, does do those statements from Dr. Harel Gadot support your opinion? A. They support my opinion that randomized controlled trials should have been done prior to launch of the TVT-Secur so that the design characteristics that made it unreasonably unsafe and unreasonably ineffective would have been known prior to launch and either the product not launched or the design characteristics fixed to make it

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	Page 198		Page 200
1	ultimately at least sponsored randomized controlled	1	MR. SNELL: Opposing.
2	trials?	2	MR. THORNBURGH: Opposing counsel.
3	A. There were initiator excuse me	3	MR. SNELL: Opposing by stipulation.
4	investigator-initiated studies that were co-funded	4	BY MR. THORNBURGH:
5	by Ethicon.	5	Q. Doctor, Exhibit P842, did you review and
6	Q. And do you know whether or not those	6	rely on that document before or that exhibit in
7	investigator-initiated studies that were sponsored	7	rendering your opinions?
8	at least financially by Ethicon supported or didn't	8	A. Yes.
9	support the safety and efficacy of the TVT-Secur	9	Q. And what about Exhibit P842 did you rely
10	product?	10	upon?
11	A. There are studies that were	11	A. Again, this is a PowerPoint presentation
12	investigator-initiated studies that did not support	12	which discusses the reasons for development, the
13	the safety and efficacy of the TVT-Secur.	13	needs for the TVT-Secur device. This is important
14	Q. And we will talk about some of those	14	in my opinions that the need for the device was not
15	studies, but we've got to take a break for changing	15	based on a safety and efficacy. These were
16	the tape.	16	based on financial decisions.
17	THE VIDEOGRAPHER: Okay. The time is 2:02	17	There was a rush to market to fill a gap
18	p.m. This is the end of Tape 2 and we're going off	18	that competition to the products that Ethicon had
19	the video record.	19	on the market, and they felt Ethicon felt that
20	(WHEREUPON, a recess was had	20	if they did not have a TVT-Secur device on the
21	from 2:02 to 2:13 p.m.)	21	market as soon as possible, they would lose market
22	THE VIDEOGRAPHER: The time is 2:13 p.m. This	22	share.
23	is the beginning of Tape 3 and we're back on the	23	MR. SNELL: Object. Move to strike the state
24	video record.	24	of mind. Go ahead.
	Page 199		Page 201
1	BY MR. THORNBURGH:	1	BY MR. THORNBURGH:
2	Q. Doctor, before we went off for break and	2	Q. And, Doctor, can you walk us through the
3	throughout the vast majority of this deposition, we	3	different slides that you believe support your
4	have been discussing your binder that you brought	4	opinions and explain how those slides support your
5	with you today, is that correct?	5	opinions, please.
6	A. Yes.	6	A. Yes. This is the fourth slide. It has
7	Q. And did you put together that binder?	7	a graph that we had looked at previously in the
8	A. Yes.	8	charter document showing the proposed decrease
9	Q. Did you highlight the portions of the	9	it's actually the next page.
10	document that you felt were important for purposes	10	Q. Okay. So, slide 5, is that where you're
11	of providing your opinions today?	11	at?
12	A. Yes.	12	A. Correct.
13	Q. And if I didn't ask you this already,	13	MR. SNELL: Let me just put an objection. I
14	maybe I thought it went without saying, but did you	14	just want to object to the document on the record
	review and rely on all of those documents that are	15	and I'll be quiet.
15	in your binder?	16	BY THE WITNESS:
15 16		1	A. Actually let's go back to the one before
	A. Yes.	17	
16	<ul><li>A. Yes.</li><li>Q. Doctor, what is the next exhibit you</li></ul>	18	that.
16 17	Q. Doctor, what is the next exhibit you		
16 17 18	Q. Doctor, what is the next exhibit you would like to discuss with the jury?	18	that.
16 17 18 19	<ul><li>Q. Doctor, what is the next exhibit you would like to discuss with the jury?</li><li>A. This is a PowerPoint presentation, an</li></ul>	18 19	that. BY MR. THORNBURGH:
16 17 18 19 20 21	<ul><li>Q. Doctor, what is the next exhibit you would like to discuss with the jury?</li><li>A. This is a PowerPoint presentation, an internal Ethicon document, regarding the reasons</li></ul>	18 19 20 21	that. BY MR. THORNBURGH: Q. Slide 4 for the record. A. Yes.
16 17 18 19 20	<ul><li>Q. Doctor, what is the next exhibit you would like to discuss with the jury?</li><li>A. This is a PowerPoint presentation, an</li></ul>	18 19 20	that. BY MR. THORNBURGH: Q. Slide 4 for the record.

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Page 202 Page 204 1 numbered, but it's the fourth slide in 1 was the first to come to -- bring -- to bring a 2 Exhibit P842. 2 synthetic polypropylene mesh to the market for use 3 3 I'm sorry. Go ahead, Doctor. in the retropubic approach? 4 A. Correct. What this document shows is a 4 A. Yes. They were the first retropubic 5 projection of what is happening with the market for 5 full-length polypropylene midurethral sling. 6 the TVT Retropubic which continues to shrink. 6 Q. And do you know whether or not Ethicon 7 7 However, Gynecare will maintain the vast majority was the first company to market a midurethral 8 of that market. 8 synthetic polypropylene sling to be implanted 9 9 through the obturator approach? However, the obturator market is going 10 to continue to grow and in order to be able to 10 A. No, they were not. 11 compete with their competitors, Gynecare needs to 11 Q. They were not the first to come to 12 have a product that will be able to compete with 12 market on the obturator, is that correct? 13 13 this expanding market and the loss of the market of A. Correct. 14 the retropubic slings. 14 Q. And did that -- do you have an 15 15 Q. Now, you've talked about the obturator understanding as to whether or not the fact that 16 16 and competition and market share. But can you they were not the first to market the obturator 17 17 device, how or if at all that impacted Ethicon's explain for the ladies and gentlemen of the jury 18 your understanding, based on your knowledge, 18 market share? 19 training and experience as well as your review of 19 MR. SNELL: Objection. 20 Ethicon's documents, sort of what was going on at 20 BY THE WITNESS: 21 this time period with the different synthetic 21 A. They were losing market share to the 22 midurethral slings that were on the market and how 22 obturator market prior to them putting an obturator 23 that may or may not have impacted Ethicon's market 23 sling on the market. 24 24 BY MR. THORNBURGH: Page 203 Page 205 1 MR. SNELL: Object. Go ahead. Q. Is this kind of what we were talking 1 2 BY THE WITNESS: 2 about earlier in the charter document? 3 A. Well, as this graphic shows is that the 3 A. Yes. 4 retropubic sling market, the one that goes behind 4 Q. And do you know or have an opinion as to 5 5 the pubic bone that I've discussed earlier in how, based on your review of the records -- strike 6 6 testimony, was becoming a less significant part of 7 7 the marketplace. And, so, if we look at this slide, 8 slide 4, it shows a "Past," "Now" and "Future" The obturator sling, which I've 8 9 discussed in earlier testimony, was becoming a 9 columns. Do you see that? 10 larger part of the midurethral sling market. 10 A. Yes. 11 However, the portion of that market for Ethicon was 11 Q. And is that what you sort of explained 12 12 that in the past where it says, it says Gynecare, not growing in the same proportion as the market 13 13 they -- for the retropubic space, they had a -- the was growing. 14 BY MR. THORNBURGH: 14 vast majority of the market share? 15 Q. Let me stop you right there for a 15 A. Yes. 16 minute. 16 Q. And you'll see that there is these sort 17 17 Was Ethicon -- so, at this point in of pie graphs are depicted in several different 18 time, there was the retropubic slings that were on 18 ways, either by color or by size, and you'll see in 19 the market, is that correct? 19 the "Past" that the size of the circle or pie is 20 A. Correct. 20 larger for Gynecare Retropubic than it is in the 21 Q. Was there also the obturator slings that 21 "Current" or "Future" columns. 22 were on the market? 22 Do you see that? 23 A. Correct. 23 MR. SNELL: Object; leading. 24 Q. And do you know whether or not Ethicon 24 BY THE WITNESS:

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	Page 206		Page 208
1	A. Correct.	1	The retropubic, see where it says
2	BY MR. THORNBURGH:	2	"Retropubic," if I describe that as one sandbox and
3	Q. And because I got an objection, can you	3	the obturator as another sandbox and the mini-sling
4	describe sort of the past, current at the time of	4	as a third sandbox, does that make sense to you?
5	this PowerPoint, and future projection concerning	5	MR. SNELL: Objection; form, leading.
6	the market share and how they're depicted in this	6	BY THE WITNESS:
7	document?	7	A. Whether it's a sandbox or a category
8	A. The retropubic market will continue to	8	or
9	decrease though Ethi Gyne Ethicare (sic) will	9	BY MR. THORNBURGH:
10	maintain its large portion of that market. The	10	Q. Three different categories.
11	obturator market continues to grow, however	11	What were the three different
12	Ethicon's share of that market is not is	12	categories what were the three different
13	actually shrinking in the future.	13	categories of products or future products that are
14	Q. Okay. And there is a little sort of	14	being described here?
15	how do you describe that? A text bubble. What	15	A. There were was the retropubic
16	does that text bubble say and does or does that	16	category, the transobturator category and the
17	have any import or relevance to your opinions?	17	mini-sling or single-incision sling category, which
18	A. What this says is that the obturator	18	the Secur fell under.
19	market will become a larger share of the	19	Q. And based on your review of this
20	midurethral sling market and because there are many	20	document and the documents internal documents,
21	competitors, it might be difficult to get customers	21	do you have an opinion as to whether or not Ethicon
22	back.	22	was attempting to maintain its market share by
23	Q. Are there any other slides in this	23	developing the third category of retro of
24	exhibit that are relevant to your opinions?	24	midurethral slings in order to preserve its market
	exhibit that the relevant to your opinions.		inducedral sings in order to preserve its market
	Page 207		Page 209
1	A. The next slide, which shows without the	1	share?
2	TVT-Secur what would is projected to happen to	2	MR. SNELL: Objection.
3	Gynecare's, which is a division of Ethicon's,	3	BY THE WITNESS:
4	market share, again, with the same tag bubble that	4	A. Yes.
5	we saw before.	5	BY MR. THORNBURGH:
6	The next slide is a projection	6	Q. Have you seen Ethicon refer to these
7	Q. And do you have an understanding of what	7	three different categories as sandboxes?
8	was expected to happen to Gynecare market share	8	MR. SNELL: Objection; leading.
9	without the TVT-Secur?	9	BY THE WITNESS:
10	A. Yes, it was projected to decrease as	10	A. Yes, I have in internal documents.
11	what's seen in this slide.	11	BY MR. THORNBURGH:
12	Q. And is there any other relevant slides	12	Q. So, when we talk about sandboxes later
	that you want to discuss concerning your opinions?	13	on and so that no one gets confused, we know that
13	and you want to discuss concerning your opinions.		
13 14	A. Yes. The next slide is a projection	14	sandbox 1 would be the retropubic midurethral sling
		14 15	sandbox 1 would be the retropubic midurethral sling products, sandbox 2 would be the obturator sling
14	A. Yes. The next slide is a projection		
14 15	A. Yes. The next slide is a projection of with the single-incision or mini-sling or	15	products, sandbox 2 would be the obturator sling
14 15 16	A. Yes. The next slide is a projection of with the single-incision or mini-sling or TVT-Secur, that Ethicon would grow that market and	15 16	products, sandbox 2 would be the obturator sling products and sandbox 3 would be the mini-slings.
14 15 16 17	A. Yes. The next slide is a projection of with the single-incision or mini-sling or TVT-Secur, that Ethicon would grow that market and be the major have the the major share in that market.	15 16 17	products, sandbox 2 would be the obturator sling products and sandbox 3 would be the mini-slings. Is that fair?  A. Yes.
14 15 16 17 18	A. Yes. The next slide is a projection of with the single-incision or mini-sling or TVT-Secur, that Ethicon would grow that market and be the major have the the major share in that market.  Q. And so and just want to understand	15 16 17 18	products, sandbox 2 would be the obturator sling products and sandbox 3 would be the mini-slings. Is that fair?  A. Yes.  MR. SNELL: Objection; leading.
14 15 16 17 18	A. Yes. The next slide is a projection of with the single-incision or mini-sling or TVT-Secur, that Ethicon would grow that market and be the major have the the major share in that market.  Q. And so and just want to understand some terminology a little bit.	15 16 17 18 19	products, sandbox 2 would be the obturator sling products and sandbox 3 would be the mini-slings. Is that fair?  A. Yes.  MR. SNELL: Objection; leading. BY MR. THORNBURGH:
14 15 16 17 18 19 20	A. Yes. The next slide is a projection of with the single-incision or mini-sling or TVT-Secur, that Ethicon would grow that market and be the major have the the major share in that market.  Q. And so and just want to understand some terminology a little bit.  Are there sort of three or three	15 16 17 18 19 20	products, sandbox 2 would be the obturator sling products and sandbox 3 would be the mini-slings. Is that fair?  A. Yes.  MR. SNELL: Objection; leading. BY MR. THORNBURGH: Q. Since I got a leading objection.
14 15 16 17 18 19 20 21	A. Yes. The next slide is a projection of with the single-incision or mini-sling or TVT-Secur, that Ethicon would grow that market and be the major have the the major share in that market.  Q. And so and just want to understand some terminology a little bit.  Are there sort of three or three different segments of the midurethral sling	15 16 17 18 19 20 21	products, sandbox 2 would be the obturator sling products and sandbox 3 would be the mini-slings. Is that fair?  A. Yes.  MR. SNELL: Objection; leading. BY MR. THORNBURGH: Q. Since I got a leading objection.  How did some of Ethicon's employees
14 15 16 17 18 19 20 21	A. Yes. The next slide is a projection of with the single-incision or mini-sling or TVT-Secur, that Ethicon would grow that market and be the major have the the major share in that market.  Q. And so and just want to understand some terminology a little bit.  Are there sort of three or three	15 16 17 18 19 20 21 22	products, sandbox 2 would be the obturator sling products and sandbox 3 would be the mini-slings. Is that fair?  A. Yes.  MR. SNELL: Objection; leading. BY MR. THORNBURGH: Q. Since I got a leading objection.

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	Page 210		Page 212
1	Q. Are there any other relevant slides that	1	less material that would be left behind in the
2	you'd like to discuss that support your opinions?	2	patient?
3	A. Yes. There's a summary slide that	3	A. At the time of implant or throughout the
4	describes the need for the TVT-Secur to reclaim	4	rest of a woman's life?
5	market share and to protect revenue.	5	Q. Well, what matters the most?
6	Q. Is that the slide that says "Summary"	6	A. Throughout the rest of a woman's life.
7	right there?	7	Q. So, do you have an opinion whether or
8	A. Yes.	8	not the TVT-Secur, mini-sling, offered patients a
9	Q. And these slides aren't numbered so for	9	synthetic polypropylene material that would result
10	the record it says "Summary" and has two boxes,	10	in less material being left behind in the patient?
11	"The TVT-Secur reclaims our market share," and "The	11	A. Well, when we look at the success rate
12	TVT-Secur protects our revenue," is that correct?	12	of the mini-sling, it is has design
13	MR. SNELL: Objection; leading.	13	characteristics that make it unreasonably not
14	BY MR. THORNBURGH:	14	effective and, therefore, they would have a
15	O. I think it's Slide No. 8.	15	recurrence of their stress incontinence and,
16	A. Yes.	16	therefore, would have the risk of having another
17	Q. And are there any other slides that	17	polypropylene sling placed that would make it that
18	support your opinion?	18	they had even more polypropylene left behind.
19	A. Yes. "Unmet Needs." The next slide	19	Q. So
20	after that is called "Needs" for the TVT-Secur.	20	MR. SNELL: Objection. Move to strike,
21	Next slide, please. Is one of the needs is	21	non-responsive.
22	"Maximum safety."	22	BY MR. THORNBURGH:
23	Q. And is it important for companies do	23	Q. So, what's the basis what's the
24	you have an opinion whether or not it's important	24	support or basis for that opinion, Doctor?
	Dama 011		
	Page 211		Page 213
1	for companies to maximize safety?	1	A. The success rate for the mini-slings.
1 2	for companies to maximize safety?  A. Yes, it is important. It's important	1 2	<ul><li>A. The success rate for the mini-slings.</li><li>Q. Would it be accurate for Ethicon to</li></ul>
	for companies to maximize safety?  A. Yes, it is important. It's important for patients to have the devices that are going to	2 3	<ul><li>A. The success rate for the mini-slings.</li><li>Q. Would it be accurate for Ethicon to represent to physicians or make a claim to</li></ul>
2 3 4	for companies to maximize safety?  A. Yes, it is important. It's important for patients to have the devices that are going to be permanently implanted in them to have	2 3 4	A. The success rate for the mini-slings.  Q. Would it be accurate for Ethicon to represent to physicians or make a claim to physicians that if you used the TVT-Secur device,
2 3 4 5	for companies to maximize safety?  A. Yes, it is important. It's important for patients to have the devices that are going to be permanently implanted in them to have characteristics that maximize safety and maximize	2 3 4 5	A. The success rate for the mini-slings.  Q. Would it be accurate for Ethicon to represent to physicians or make a claim to physicians that if you used the TVT-Secur device, less foreign body material will be left behind in
2 3 4 5 6	for companies to maximize safety?  A. Yes, it is important. It's important for patients to have the devices that are going to be permanently implanted in them to have characteristics that maximize safety and maximize efficacy.	2 3 4 5 6	A. The success rate for the mini-slings.  Q. Would it be accurate for Ethicon to represent to physicians or make a claim to physicians that if you used the TVT-Secur device, less foreign body material will be left behind in your patients? Would that be accurate?
2 3 4 5	for companies to maximize safety?  A. Yes, it is important. It's important for patients to have the devices that are going to be permanently implanted in them to have characteristics that maximize safety and maximize efficacy.  Q. Now, I want to talk to you real briefly	2 3 4 5	A. The success rate for the mini-slings.  Q. Would it be accurate for Ethicon to represent to physicians or make a claim to physicians that if you used the TVT-Secur device, less foreign body material will be left behind in your patients? Would that be accurate?  MR. SNELL: Objection.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	for companies to maximize safety?  A. Yes, it is important. It's important for patients to have the devices that are going to be permanently implanted in them to have characteristics that maximize safety and maximize efficacy.  Q. Now, I want to talk to you real briefly about the third bullet point that says, "Less material left behind in the patient." Do you see that?  A. Yes.  Q. Isn't it true, Doctor, that if you create a mini-sling, a shorter sling, that you're leaving less foreign body, less synthetic material behind in a patient's body?  MR. SNELL: Objection; leading. BY THE WITNESS:  A. There would be the same amount of material in the vagina, but there will not be foreign material in areas where the sling is not. BY MR. THORNBURGH:  Q. Do you have an opinion whether or not	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. The success rate for the mini-slings.  Q. Would it be accurate for Ethicon to represent to physicians or make a claim to physicians that if you used the TVT-Secur device, less foreign body material will be left behind in your patients? Would that be accurate?  MR. SNELL: Objection.  BY THE WITNESS:  A. It is not completely accurate because of the failure rate increases the risk of having another surgery to treat the recurrence or the continuation of incontinence, and that increases the risk of another midurethral sling being placed, which increases the risk or increases the amount of polypropylene that is left in their body.  BY MR. THORNBURGH:  Q. We are going to get to this in a little bit, but do you have an opinion about what the efficacy rate or the failure rate was for the TVT-Secur product?  A. Well, there are some studies that show a better efficacy rate. There are many studies that
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	for companies to maximize safety?  A. Yes, it is important. It's important for patients to have the devices that are going to be permanently implanted in them to have characteristics that maximize safety and maximize efficacy.  Q. Now, I want to talk to you real briefly about the third bullet point that says, "Less material left behind in the patient." Do you see that?  A. Yes.  Q. Isn't it true, Doctor, that if you create a mini-sling, a shorter sling, that you're leaving less foreign body, less synthetic material behind in a patient's body?  MR. SNELL: Objection; leading. BY THE WITNESS:  A. There would be the same amount of material in the vagina, but there will not be foreign material in areas where the sling is not. BY MR. THORNBURGH:  Q. Do you have an opinion whether or not Ethicon's mini-sling, the TVT-Secur, resulted in	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. The success rate for the mini-slings.  Q. Would it be accurate for Ethicon to represent to physicians or make a claim to physicians that if you used the TVT-Secur device, less foreign body material will be left behind in your patients? Would that be accurate?  MR. SNELL: Objection.  BY THE WITNESS:  A. It is not completely accurate because of the failure rate increases the risk of having another surgery to treat the recurrence or the continuation of incontinence, and that increases the risk of another midurethral sling being placed, which increases the risk or increases the amount of polypropylene that is left in their body.  BY MR. THORNBURGH:  Q. We are going to get to this in a little bit, but do you have an opinion about what the efficacy rate or the failure rate was for the TVT-Secur product?  A. Well, there are some studies that show a better efficacy rate. There are many studies that show an accumulative efficacy rate of 75% or less.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	for companies to maximize safety?  A. Yes, it is important. It's important for patients to have the devices that are going to be permanently implanted in them to have characteristics that maximize safety and maximize efficacy.  Q. Now, I want to talk to you real briefly about the third bullet point that says, "Less material left behind in the patient." Do you see that?  A. Yes.  Q. Isn't it true, Doctor, that if you create a mini-sling, a shorter sling, that you're leaving less foreign body, less synthetic material behind in a patient's body?  MR. SNELL: Objection; leading. BY THE WITNESS:  A. There would be the same amount of material in the vagina, but there will not be foreign material in areas where the sling is not. BY MR. THORNBURGH:  Q. Do you have an opinion whether or not	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. The success rate for the mini-slings.  Q. Would it be accurate for Ethicon to represent to physicians or make a claim to physicians that if you used the TVT-Secur device, less foreign body material will be left behind in your patients? Would that be accurate?  MR. SNELL: Objection.  BY THE WITNESS:  A. It is not completely accurate because of the failure rate increases the risk of having another surgery to treat the recurrence or the continuation of incontinence, and that increases the risk of another midurethral sling being placed, which increases the risk or increases the amount of polypropylene that is left in their body.  BY MR. THORNBURGH:  Q. We are going to get to this in a little bit, but do you have an opinion about what the efficacy rate or the failure rate was for the TVT-Secur product?  A. Well, there are some studies that show a better efficacy rate. There are many studies that

	Page 214		Page 216
1	that looked at efficacy?	1	MR. SNELL: Object.
2	A. Yes.	2	BY THE WITNESS:
3	Q. And what was the longest term study that	3	A. No, they were not made to physicians.
4	you looked at regarding efficacy of the TVT-Secur	4	BY MR. THORNBURGH:
5	product?	5	Q. Did Ethicon ever I'm just trying to
6	A. Five years.	6	understand this exhibit slide that says "Needs."
7	Q. And what study was that?	7	It says the needs and they're talking about the
8	A. There are two. One is the Tommaselli	8	third generation mini-slings, right?
9	study and one is the Haab study.	9	A. The third generation slings, yes.
10	Q. And did the how does or does the Haab	10	Q. Okay. And it says, "Needs. Maximize
11	study or how does the Haab study support, if at	11	safety. Minimal passage through tissues. Less
12	all, your opinion that patients who have the	12	material left behind in the patient. No exit.
13	TVT-Secur device are at risk of having failure and	13	Versatility," and then the last one says, "But same
14	more polypropylene material implanted to treat the	14	great efficacy."
15	failed procedure?	15	Did I read that correctly?
16	MR. SNELL: Object; leading.	16	A. Yes.
17	BY THE WITNESS:	17	Q. Do you know based on your review of
18	A. The Haab study showed a 30% success rate	18	Ethicon's internal documents whether they had made
19	after four and a half years and, therefore, those	19	the claim to physicians that the TVT-Secur would
20	patients would be at risk for requiring another	20	have the same or equivalent efficacy as its other
21	surgery to treat their recurrent stress urinary	21	TVT first and second generation products?
22	incontinence.	22	MR. SNELL: Object. Go ahead.
23	BY MR. THORNBURGH:	23	BY THE WITNESS:
24	Q. So, a 30% success rate?	24	A. Yes, they did.
	Page 215		D 017
	1490 213		Page 217
1	A. 30% success rate.	1	BY MR. THORNBURGH:
1 2	A. 30% success rate.	1 2	
	A. 30% success rate.		BY MR. THORNBURGH:
2	<ul><li>A. 30% success rate.</li><li>Q. So, what's that failure rate?</li></ul>	2	BY MR. THORNBURGH: Q. And was that claim correct?
2	<ul><li>A. 30% success rate.</li><li>Q. So, what's that failure rate?</li><li>A. 70%.</li><li>Q. So, does that mean what does that</li></ul>	2 3	BY MR. THORNBURGH: Q. And was that claim correct? A. No, it was not.
2 3 4	<ul><li>A. 30% success rate.</li><li>Q. So, what's that failure rate?</li><li>A. 70%.</li></ul>	2 3 4	BY MR. THORNBURGH:  Q. And was that claim correct?  A. No, it was not.  Q. And what's the basis for your opinion?
2 3 4 5	<ul> <li>A. 30% success rate.</li> <li>Q. So, what's that failure rate?</li> <li>A. 70%.</li> <li>Q. So, does that mean what does that mean if we're talking about real patients? If</li> </ul>	2 3 4 5	BY MR. THORNBURGH: Q. And was that claim correct? A. No, it was not. Q. And what's the basis for your opinion? A. The review of the literature.
2 3 4 5 6	<ul> <li>A. 30% success rate.</li> <li>Q. So, what's that failure rate?</li> <li>A. 70%.</li> <li>Q. So, does that mean what does that mean if we're talking about real patients? If there are ten patients who were going to undergo a</li> </ul>	2 3 4 5 6	BY MR. THORNBURGH: Q. And was that claim correct? A. No, it was not. Q. And what's the basis for your opinion? A. The review of the literature. Q. Are there any other slides you'd like to discuss with respect to Exhibit P04 0842 that
2 3 4 5 6 7	<ul> <li>A. 30% success rate.</li> <li>Q. So, what's that failure rate?</li> <li>A. 70%.</li> <li>Q. So, does that mean what does that mean if we're talking about real patients? If there are ten patients who were going to undergo a procedure to put the TVT-Secur device in their</li> </ul>	2 3 4 5 6 7	BY MR. THORNBURGH:  Q. And was that claim correct?  A. No, it was not.  Q. And what's the basis for your opinion?  A. The review of the literature.  Q. Are there any other slides you'd like to
2 3 4 5 6 7 8	<ul> <li>A. 30% success rate.</li> <li>Q. So, what's that failure rate?</li> <li>A. 70%.</li> <li>Q. So, does that mean what does that mean if we're talking about real patients? If there are ten patients who were going to undergo a procedure to put the TVT-Secur device in their bodies, how many of those ten patients were at risk</li> </ul>	2 3 4 5 6 7 8	BY MR. THORNBURGH:  Q. And was that claim correct?  A. No, it was not.  Q. And what's the basis for your opinion?  A. The review of the literature.  Q. Are there any other slides you'd like to discuss with respect to Exhibit P04 0842 that you believe support your opinions?
2 3 4 5 6 7 8 9	<ul> <li>A. 30% success rate.</li> <li>Q. So, what's that failure rate?</li> <li>A. 70%.</li> <li>Q. So, does that mean what does that mean if we're talking about real patients? If there are ten patients who were going to undergo a procedure to put the TVT-Secur device in their bodies, how many of those ten patients were at risk of suffering a failure if they underwent TVT-Secur</li> </ul>	2 3 4 5 6 7 8	BY MR. THORNBURGH:  Q. And was that claim correct?  A. No, it was not.  Q. And what's the basis for your opinion?  A. The review of the literature.  Q. Are there any other slides you'd like to discuss with respect to Exhibit P04 0842 that you believe support your opinions?  A. The "Testing to Date."
2 3 4 5 6 7 8 9	<ul> <li>A. 30% success rate.</li> <li>Q. So, what's that failure rate?</li> <li>A. 70%.</li> <li>Q. So, does that mean what does that mean if we're talking about real patients? If there are ten patients who were going to undergo a procedure to put the TVT-Secur device in their bodies, how many of those ten patients were at risk of suffering a failure if they underwent TVT-Secur surgery?</li> </ul>	2 3 4 5 6 7 8 9	BY MR. THORNBURGH:  Q. And was that claim correct?  A. No, it was not.  Q. And what's the basis for your opinion?  A. The review of the literature.  Q. Are there any other slides you'd like to discuss with respect to Exhibit P04 0842 that you believe support your opinions?  A. The "Testing to Date."  MR. THORNBURGH: And what slide is this, Tom,
2 3 4 5 6 7 8 9 10	<ul> <li>A. 30% success rate.</li> <li>Q. So, what's that failure rate?</li> <li>A. 70%.</li> <li>Q. So, does that mean what does that mean if we're talking about real patients? If there are ten patients who were going to undergo a procedure to put the TVT-Secur device in their bodies, how many of those ten patients were at risk of suffering a failure if they underwent TVT-Secur surgery?</li> <li>MR. SNELL: Object.</li> </ul>	2 3 4 5 6 7 8 9 10	BY MR. THORNBURGH:  Q. And was that claim correct?  A. No, it was not.  Q. And what's the basis for your opinion?  A. The review of the literature.  Q. Are there any other slides you'd like to discuss with respect to Exhibit P04 0842 that you believe support your opinions?  A. The "Testing to Date."  MR. THORNBURGH: And what slide is this, Tom, for the record? So people could find it.
2 3 4 5 6 7 8 9 10 11	<ul> <li>A. 30% success rate.</li> <li>Q. So, what's that failure rate?</li> <li>A. 70%.</li> <li>Q. So, does that mean what does that mean if we're talking about real patients? If there are ten patients who were going to undergo a procedure to put the TVT-Secur device in their bodies, how many of those ten patients were at risk of suffering a failure if they underwent TVT-Secur surgery?</li> <li>MR. SNELL: Object.</li> <li>BY THE WITNESS:</li> </ul>	2 3 4 5 6 7 8 9 10 11	BY MR. THORNBURGH:  Q. And was that claim correct?  A. No, it was not.  Q. And what's the basis for your opinion?  A. The review of the literature.  Q. Are there any other slides you'd like to discuss with respect to Exhibit P04 0842 that you believe support your opinions?  A. The "Testing to Date."  MR. THORNBURGH: And what slide is this, Tom, for the record? So people could find it.  MR. BODYZIAK: I believe it's 16.
2 3 4 5 6 7 8 9 10 11 12 13	A. 30% success rate. Q. So, what's that failure rate? A. 70%. Q. So, does that mean what does that mean if we're talking about real patients? If there are ten patients who were going to undergo a procedure to put the TVT-Secur device in their bodies, how many of those ten patients were at risk of suffering a failure if they underwent TVT-Secur surgery?  MR. SNELL: Object. BY THE WITNESS: A. Seven.	2 3 4 5 6 7 8 9 10 11 12 13	BY MR. THORNBURGH:  Q. And was that claim correct?  A. No, it was not.  Q. And what's the basis for your opinion?  A. The review of the literature.  Q. Are there any other slides you'd like to discuss with respect to Exhibit P04 0842 that you believe support your opinions?  A. The "Testing to Date."  MR. THORNBURGH: And what slide is this, Tom, for the record? So people could find it.  MR. BODYZIAK: I believe it's 16.  BY MR. THORNBURGH:
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2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. 30% success rate. Q. So, what's that failure rate? A. 70%. Q. So, does that mean what does that mean if we're talking about real patients? If there are ten patients who were going to undergo a procedure to put the TVT-Secur device in their bodies, how many of those ten patients were at risk of suffering a failure if they underwent TVT-Secur surgery?  MR. SNELL: Object. BY THE WITNESS: A. Seven. BY MR. THORNBURGH: Q. So, seven out of ten?	2 3 4 5 6 7 8 9 10 11 12 13 14	BY MR. THORNBURGH:  Q. And was that claim correct?  A. No, it was not.  Q. And what's the basis for your opinion?  A. The review of the literature.  Q. Are there any other slides you'd like to discuss with respect to Exhibit P04 0842 that you believe support your opinions?  A. The "Testing to Date."  MR. THORNBURGH: And what slide is this, Tom, for the record? So people could find it.  MR. BODYZIAK: I believe it's 16.  BY MR. THORNBURGH:  Q. Slide 16. It says "Testing to Date" at the top?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. 30% success rate. Q. So, what's that failure rate? A. 70%. Q. So, does that mean what does that mean if we're talking about real patients? If there are ten patients who were going to undergo a procedure to put the TVT-Secur device in their bodies, how many of those ten patients were at risk of suffering a failure if they underwent TVT-Secur surgery?  MR. SNELL: Object. BY THE WITNESS: A. Seven. BY MR. THORNBURGH: Q. So, seven out of ten? A. Correct. Q. And how many of those patients were at risk of having to undergo a second operation to	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	BY MR. THORNBURGH: Q. And was that claim correct? A. No, it was not. Q. And what's the basis for your opinion? A. The review of the literature. Q. Are there any other slides you'd like to discuss with respect to Exhibit P04 0842 that you believe support your opinions? A. The "Testing to Date." MR. THORNBURGH: And what slide is this, Tom, for the record? So people could find it. MR. BODYZIAK: I believe it's 16. BY MR. THORNBURGH: Q. Slide 16. It says "Testing to Date" at the top? A. Yes. Q. Okay. And how does this slide support your opinions, if at all?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. 30% success rate. Q. So, what's that failure rate? A. 70%. Q. So, does that mean what does that mean if we're talking about real patients? If there are ten patients who were going to undergo a procedure to put the TVT-Secur device in their bodies, how many of those ten patients were at risk of suffering a failure if they underwent TVT-Secur surgery?  MR. SNELL: Object. BY THE WITNESS: A. Seven. BY MR. THORNBURGH: Q. So, seven out of ten? A. Correct. Q. And how many of those patients were at risk of having to undergo a second operation to implant more synthetic material to treat their	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	BY MR. THORNBURGH:  Q. And was that claim correct?  A. No, it was not.  Q. And what's the basis for your opinion?  A. The review of the literature.  Q. Are there any other slides you'd like to discuss with respect to Exhibit P04 0842 that you believe support your opinions?  A. The "Testing to Date."  MR. THORNBURGH: And what slide is this, Tom, for the record? So people could find it.  MR. BODYZIAK: I believe it's 16.  BY MR. THORNBURGH:  Q. Slide 16. It says "Testing to Date" at the top?  A. Yes.  Q. Okay. And how does this slide support your opinions, if at all?  A. This supports my opinions that the
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. 30% success rate. Q. So, what's that failure rate? A. 70%. Q. So, does that mean what does that mean if we're talking about real patients? If there are ten patients who were going to undergo a procedure to put the TVT-Secur device in their bodies, how many of those ten patients were at risk of suffering a failure if they underwent TVT-Secur surgery?  MR. SNELL: Object. BY THE WITNESS: A. Seven. BY MR. THORNBURGH: Q. So, seven out of ten? A. Correct. Q. And how many of those patients were at risk of having to undergo a second operation to implant more synthetic material to treat their stress urinary incontinence?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	BY MR. THORNBURGH:  Q. And was that claim correct?  A. No, it was not.  Q. And what's the basis for your opinion?  A. The review of the literature.  Q. Are there any other slides you'd like to discuss with respect to Exhibit P04 0842 that you believe support your opinions?  A. The "Testing to Date."  MR. THORNBURGH: And what slide is this, Tom, for the record? So people could find it.  MR. BODYZIAK: I believe it's 16.  BY MR. THORNBURGH:  Q. Slide 16. It says "Testing to Date" at the top?  A. Yes.  Q. Okay. And how does this slide support your opinions, if at all?  A. This supports my opinions that the TVT-Secur was not adequately tested prior to
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. 30% success rate. Q. So, what's that failure rate? A. 70%. Q. So, does that mean what does that mean if we're talking about real patients? If there are ten patients who were going to undergo a procedure to put the TVT-Secur device in their bodies, how many of those ten patients were at risk of suffering a failure if they underwent TVT-Secur surgery?  MR. SNELL: Object. BY THE WITNESS: A. Seven. BY MR. THORNBURGH: Q. So, seven out of ten? A. Correct. Q. And how many of those patients were at risk of having to undergo a second operation to implant more synthetic material to treat their stress urinary incontinence? A. Potentially seven out of ten.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY MR. THORNBURGH:  Q. And was that claim correct?  A. No, it was not.  Q. And what's the basis for your opinion?  A. The review of the literature.  Q. Are there any other slides you'd like to discuss with respect to Exhibit P04 0842 that you believe support your opinions?  A. The "Testing to Date."  MR. THORNBURGH: And what slide is this, Tom, for the record? So people could find it.  MR. BODYZIAK: I believe it's 16.  BY MR. THORNBURGH:  Q. Slide 16. It says "Testing to Date" at the top?  A. Yes.  Q. Okay. And how does this slide support your opinions, if at all?  A. This supports my opinions that the TVT-Secur was not adequately tested prior to launch.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. 30% success rate. Q. So, what's that failure rate? A. 70%. Q. So, does that mean what does that mean if we're talking about real patients? If there are ten patients who were going to undergo a procedure to put the TVT-Secur device in their bodies, how many of those ten patients were at risk of suffering a failure if they underwent TVT-Secur surgery?  MR. SNELL: Object. BY THE WITNESS: A. Seven. BY MR. THORNBURGH: Q. So, seven out of ten? A. Correct. Q. And how many of those patients were at risk of having to undergo a second operation to implant more synthetic material to treat their stress urinary incontinence? A. Potentially seven out of ten. Q. So, we have these "Needs" here, and are	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MR. THORNBURGH: Q. And was that claim correct? A. No, it was not. Q. And what's the basis for your opinion? A. The review of the literature. Q. Are there any other slides you'd like to discuss with respect to Exhibit P04 0842 that you believe support your opinions? A. The "Testing to Date." MR. THORNBURGH: And what slide is this, Tom, for the record? So people could find it. MR. BODYZIAK: I believe it's 16. BY MR. THORNBURGH: Q. Slide 16. It says "Testing to Date" at the top? A. Yes. Q. Okay. And how does this slide support your opinions, if at all? A. This supports my opinions that the TVT-Secur was not adequately tested prior to launch. It describes that there was an animal

55 (Pages 214 to 217)

	Page 218		Page 220
1	the anchors and the pull-out force of the anchors,	1	Q. Is this the same design validation
2	cadaver labs, an infection analysis, a second	2	studies are you aware whether or not this is the
3	animal study was underway and there was some	3	same design validation studies that Mark Yale wrote
4	testing between mechanical-cut and laser-cut	4	about being concerned that there was a steaming
5	laser cutting that was underway at the time of this	5	pile of blank?
6	PowerPoint presentation.	6	A. Yes.
7	Q. Okay. And Tom has the slide pulled up	7	MR. SNELL: Objection.
8	real quick, but I just want to ask really quick.	8	BY MR. THORNBURGH:
9	The first two bullet points that say	9	Q. Did the cadaveric lab, any cadaveric
10	"Animal - Pull out force studies, Animal histology	10	lab, including the labs that were done in the
11	studies," was that the first animal study that you	11	design validation phase, did any of those support
12	had discussed earlier?	12	the safety and efficacy of the TVT-Secur product?
13	A. Yes.	13	A. No.
14	Q. And that was what product did that	14	Q. The next bullet point says, "Infection
15	study test?	15	risk analysis." Are you aware of that study?
16	MR. SNELL: Object.	16	A. I recall seeing the data from that.
17	BY THE WITNESS:	17	Q. Did the infection risk analysis support
18	A. The TVT X, which was 12 centimeters and	18	the safety or efficacy of the TVT-Secur product as
19	did not have the final embodiment of the fleece	19	for treatment of stress urinary incontinence in
20	ends that ultimately are in the TVT-Secur.	20	live human women?
21	BY MR. THORNBURGH:	21	A. No.
22	Q. Would it be appropriate, do you have an	22	Q. Why is that?
23	opinion strike that.	23	A. It was not done in live human women.
24	Do you have an opinion whether or not it	24	Q. Was it done in animals, an animal?
2.1	Do you have an opinion whether or not it	2.1	Q. Was it done in animals, an animal:
	D 010		
	Page 219		Page 221
1	would be appropriate for Ethicon to represent to	1	Page 221  A. It was done in a laboratory setting.
1 2	would be appropriate for Ethicon to represent to the world or to physicians that the TVT X studies	1 2	<ul><li>A. It was done in a laboratory setting.</li><li>Q. And the next bullet point says, "Second</li></ul>
	would be appropriate for Ethicon to represent to the world or to physicians that the TVT X studies or the results from the TVT X studies supported the		<ul><li>A. It was done in a laboratory setting.</li><li>Q. And the next bullet point says, "Second animal study underway."</li></ul>
2	would be appropriate for Ethicon to represent to the world or to physicians that the TVT X studies	2	<ul><li>A. It was done in a laboratory setting.</li><li>Q. And the next bullet point says, "Second</li></ul>
2 3	would be appropriate for Ethicon to represent to the world or to physicians that the TVT X studies or the results from the TVT X studies supported the efficacy or safety of the TVT-Secur product?  MR. SNELL: Object.	2 3	<ul><li>A. It was done in a laboratory setting.</li><li>Q. And the next bullet point says, "Second animal study underway."</li></ul>
2 3 4	would be appropriate for Ethicon to represent to the world or to physicians that the TVT X studies or the results from the TVT X studies supported the efficacy or safety of the TVT-Secur product?  MR. SNELL: Object. BY THE WITNESS:	2 3 4	<ul> <li>A. It was done in a laboratory setting.</li> <li>Q. And the next bullet point says, "Second animal study underway." Are you aware what animal study that was? A. A if I recall, that was another sheep</li> </ul>
2 3 4 5	would be appropriate for Ethicon to represent to the world or to physicians that the TVT X studies or the results from the TVT X studies supported the efficacy or safety of the TVT-Secur product?  MR. SNELL: Object. BY THE WITNESS:  A. I do have an opinion.	2 3 4 5	<ul> <li>A. It was done in a laboratory setting.</li> <li>Q. And the next bullet point says, "Second animal study underway." Are you aware what animal study that was? A. A if I recall, that was another sheep cadaver study.</li> </ul>
2 3 4 5 6	would be appropriate for Ethicon to represent to the world or to physicians that the TVT X studies or the results from the TVT X studies supported the efficacy or safety of the TVT-Secur product?  MR. SNELL: Object. BY THE WITNESS:	2 3 4 5 6	<ul> <li>A. It was done in a laboratory setting.</li> <li>Q. And the next bullet point says, "Second animal study underway." Are you aware what animal study that was? A. A if I recall, that was another sheep cadaver study. Q. And did the second sheep cadaver study</li> </ul>
2 3 4 5 6 7	would be appropriate for Ethicon to represent to the world or to physicians that the TVT X studies or the results from the TVT X studies supported the efficacy or safety of the TVT-Secur product?  MR. SNELL: Object. BY THE WITNESS:  A. I do have an opinion. BY MR. THORNBURGH: Q. What's that opinion?	2 3 4 5 6 7	A. It was done in a laboratory setting.  Q. And the next bullet point says, "Second animal study underway."  Are you aware what animal study that was?  A. A if I recall, that was another sheep cadaver study.  Q. And did the second sheep cadaver study support the safety or efficacy of the TVT-Secur
2 3 4 5 6 7 8 9	would be appropriate for Ethicon to represent to the world or to physicians that the TVT X studies or the results from the TVT X studies supported the efficacy or safety of the TVT-Secur product?  MR. SNELL: Object. BY THE WITNESS:  A. I do have an opinion. BY MR. THORNBURGH: Q. What's that opinion? A. It does not support the safety and	2 3 4 5 6 7 8 9	A. It was done in a laboratory setting.  Q. And the next bullet point says, "Second animal study underway."  Are you aware what animal study that was?  A. A if I recall, that was another sheep cadaver study.  Q. And did the second sheep cadaver study support the safety or efficacy of the TVT-Secur product for permanent implantation in women?
2 3 4 5 6 7 8 9 10	would be appropriate for Ethicon to represent to the world or to physicians that the TVT X studies or the results from the TVT X studies supported the efficacy or safety of the TVT-Secur product?  MR. SNELL: Object. BY THE WITNESS:  A. I do have an opinion. BY MR. THORNBURGH: Q. What's that opinion? A. It does not support the safety and efficacy of the TVT-Secur.	2 3 4 5 6 7 8 9 10	<ul> <li>A. It was done in a laboratory setting.</li> <li>Q. And the next bullet point says, "Second animal study underway." Are you aware what animal study that was? A. A if I recall, that was another sheep cadaver study. Q. And did the second sheep cadaver study support the safety or efficacy of the TVT-Secur product for permanent implantation in women? A. No.</li> </ul>
2 3 4 5 6 7 8 9 10 11 12	would be appropriate for Ethicon to represent to the world or to physicians that the TVT X studies or the results from the TVT X studies supported the efficacy or safety of the TVT-Secur product?  MR. SNELL: Object. BY THE WITNESS:  A. I do have an opinion. BY MR. THORNBURGH: Q. What's that opinion? A. It does not support the safety and efficacy of the TVT-Secur. Q. Was the TVT X even the same product at	2 3 4 5 6 7 8 9 10 11 12	A. It was done in a laboratory setting.  Q. And the next bullet point says, "Second animal study underway."  Are you aware what animal study that was?  A. A if I recall, that was another sheep cadaver study.  Q. And did the second sheep cadaver study support the safety or efficacy of the TVT-Secur product for permanent implantation in women?  A. No.  Q. The last bullet point says, "Laser
2 3 4 5 6 7 8 9 10 11 12 13	would be appropriate for Ethicon to represent to the world or to physicians that the TVT X studies or the results from the TVT X studies supported the efficacy or safety of the TVT-Secur product?  MR. SNELL: Object. BY THE WITNESS:  A. I do have an opinion. BY MR. THORNBURGH: Q. What's that opinion? A. It does not support the safety and efficacy of the TVT-Secur. Q. Was the TVT X even the same product at all?	2 3 4 5 6 7 8 9 10 11 12	A. It was done in a laboratory setting.  Q. And the next bullet point says, "Second animal study underway."  Are you aware what animal study that was?  A. A if I recall, that was another sheep cadaver study.  Q. And did the second sheep cadaver study support the safety or efficacy of the TVT-Secur product for permanent implantation in women?  A. No.  Q. The last bullet point says, "Laser versus mechanical testing underway."
2 3 4 5 6 7 8 9 10 11 12	would be appropriate for Ethicon to represent to the world or to physicians that the TVT X studies or the results from the TVT X studies supported the efficacy or safety of the TVT-Secur product?  MR. SNELL: Object. BY THE WITNESS:  A. I do have an opinion. BY MR. THORNBURGH: Q. What's that opinion? A. It does not support the safety and efficacy of the TVT-Secur. Q. Was the TVT X even the same product at all? A. No.	2 3 4 5 6 7 8 9 10 11 12 13 14	A. It was done in a laboratory setting.  Q. And the next bullet point says, "Second animal study underway."  Are you aware what animal study that was?  A. A if I recall, that was another sheep cadaver study.  Q. And did the second sheep cadaver study support the safety or efficacy of the TVT-Secur product for permanent implantation in women?  A. No.  Q. The last bullet point says, "Laser versus mechanical testing underway."  Did any of the laser versus mechanical
2 3 4 5 6 7 8 9 10 11 12 13 14	would be appropriate for Ethicon to represent to the world or to physicians that the TVT X studies or the results from the TVT X studies supported the efficacy or safety of the TVT-Secur product?  MR. SNELL: Object. BY THE WITNESS:  A. I do have an opinion. BY MR. THORNBURGH: Q. What's that opinion? A. It does not support the safety and efficacy of the TVT-Secur. Q. Was the TVT X even the same product at all?  A. No. Q. The next third bullet point says,	2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. It was done in a laboratory setting.  Q. And the next bullet point says, "Second animal study underway."  Are you aware what animal study that was?  A. A if I recall, that was another sheep cadaver study.  Q. And did the second sheep cadaver study support the safety or efficacy of the TVT-Secur product for permanent implantation in women?  A. No.  Q. The last bullet point says, "Laser versus mechanical testing underway."  Did any of the laser versus mechanical testing support the safety of the TVT-Secur as a
2 3 4 5 6 7 8 9 10 11 12 13 14 15	would be appropriate for Ethicon to represent to the world or to physicians that the TVT X studies or the results from the TVT X studies supported the efficacy or safety of the TVT-Secur product?  MR. SNELL: Object. BY THE WITNESS:  A. I do have an opinion. BY MR. THORNBURGH: Q. What's that opinion? A. It does not support the safety and efficacy of the TVT-Secur. Q. Was the TVT X even the same product at all?  A. No. Q. The next third bullet point says, "9 cadaveric labs (sizing/pull out)."	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. It was done in a laboratory setting. Q. And the next bullet point says, "Second animal study underway."  Are you aware what animal study that was?  A. A if I recall, that was another sheep cadaver study. Q. And did the second sheep cadaver study support the safety or efficacy of the TVT-Secur product for permanent implantation in women? A. No. Q. The last bullet point says, "Laser versus mechanical testing underway."  Did any of the laser versus mechanical testing support the safety of the TVT-Secur as a permanent implant in the female woman female
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	would be appropriate for Ethicon to represent to the world or to physicians that the TVT X studies or the results from the TVT X studies supported the efficacy or safety of the TVT-Secur product?  MR. SNELL: Object. BY THE WITNESS:  A. I do have an opinion. BY MR. THORNBURGH: Q. What's that opinion? A. It does not support the safety and efficacy of the TVT-Secur. Q. Was the TVT X even the same product at all?  A. No. Q. The next third bullet point says, "9 cadaveric labs (sizing/pull out)."  Do you see that? A. Yes. Q. Is this the design validation studies that you discussed earlier with the jury?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. It was done in a laboratory setting. Q. And the next bullet point says, "Second animal study underway."  Are you aware what animal study that was?  A. A if I recall, that was another sheep cadaver study.  Q. And did the second sheep cadaver study support the safety or efficacy of the TVT-Secur product for permanent implantation in women?  A. No. Q. The last bullet point says, "Laser versus mechanical testing underway."  Did any of the laser versus mechanical testing support the safety of the TVT-Secur as a permanent implant in the female woman female body?  A. No. Q. What's the next slide in your presentation that you want to discuss?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	would be appropriate for Ethicon to represent to the world or to physicians that the TVT X studies or the results from the TVT X studies supported the efficacy or safety of the TVT-Secur product?  MR. SNELL: Object.  BY THE WITNESS:  A. I do have an opinion.  BY MR. THORNBURGH:  Q. What's that opinion?  A. It does not support the safety and efficacy of the TVT-Secur.  Q. Was the TVT X even the same product at all?  A. No.  Q. The next third bullet point says,  "9 cadaveric labs (sizing/pull out)."  Do you see that?  A. Yes.  Q. Is this the design validation studies that you discussed earlier with the jury?  A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. It was done in a laboratory setting. Q. And the next bullet point says, "Second animal study underway."  Are you aware what animal study that was?  A. A if I recall, that was another sheep cadaver study. Q. And did the second sheep cadaver study support the safety or efficacy of the TVT-Secur product for permanent implantation in women?  A. No. Q. The last bullet point says, "Laser versus mechanical testing underway."  Did any of the laser versus mechanical testing support the safety of the TVT-Secur as a permanent implant in the female woman female body?  A. No. Q. What's the next slide in your presentation that you want to discuss?  A. The slide of the competitor mini-slings
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	would be appropriate for Ethicon to represent to the world or to physicians that the TVT X studies or the results from the TVT X studies supported the efficacy or safety of the TVT-Secur product?  MR. SNELL: Object.  BY THE WITNESS:  A. I do have an opinion.  BY MR. THORNBURGH:  Q. What's that opinion?  A. It does not support the safety and efficacy of the TVT-Secur.  Q. Was the TVT X even the same product at all?  A. No.  Q. The next third bullet point says,  "9 cadaveric labs (sizing/pull out)."  Do you see that?  A. Yes.  Q. Is this the design validation studies that you discussed earlier with the jury?  A. Yes.  Q. Is this the same design validation	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. It was done in a laboratory setting.  Q. And the next bullet point says, "Second animal study underway."  Are you aware what animal study that was?  A. A if I recall, that was another sheep cadaver study.  Q. And did the second sheep cadaver study support the safety or efficacy of the TVT-Secur product for permanent implantation in women?  A. No.  Q. The last bullet point says, "Laser versus mechanical testing underway."  Did any of the laser versus mechanical testing support the safety of the TVT-Secur as a permanent implant in the female woman female body?  A. No.  Q. What's the next slide in your presentation that you want to discuss?  A. The slide of the competitor mini-slings that were either launched or proposed to be
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	would be appropriate for Ethicon to represent to the world or to physicians that the TVT X studies or the results from the TVT X studies supported the efficacy or safety of the TVT-Secur product?  MR. SNELL: Object.  BY THE WITNESS:  A. I do have an opinion.  BY MR. THORNBURGH:  Q. What's that opinion?  A. It does not support the safety and efficacy of the TVT-Secur.  Q. Was the TVT X even the same product at all?  A. No.  Q. The next third bullet point says,  "9 cadaveric labs (sizing/pull out)."  Do you see that?  A. Yes.  Q. Is this the design validation studies that you discussed earlier with the jury?  A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. It was done in a laboratory setting. Q. And the next bullet point says, "Second animal study underway."  Are you aware what animal study that was?  A. A if I recall, that was another sheep cadaver study. Q. And did the second sheep cadaver study support the safety or efficacy of the TVT-Secur product for permanent implantation in women?  A. No. Q. The last bullet point says, "Laser versus mechanical testing underway."  Did any of the laser versus mechanical testing support the safety of the TVT-Secur as a permanent implant in the female woman female body?  A. No. Q. What's the next slide in your presentation that you want to discuss?  A. The slide of the competitor mini-slings

	Page 222		Page 224
1	whether or not these were some of the competitors	1	Q. And would Phase 3 occur after the
2	of Ethicon?	2	TVT-Secur was launched on the market?
3	A. Yes.	3	A. Yes.
4	Q. What's the next slide you'd like to	4	Q. Doctor, have you ever heard of the
5	discuss?	5	acronym R & D?
6	A. The "Product Strategy."	6	A. Yes.
7	Q. Okay. And it's a slide called "Product	7	Q. What does R & D stand for, Doctor?
8	Strategy," and how does this document support your	8	A. Research and development.
9	opinions, if at all?	9	Q. Based on your knowledge, training and
10	A. Well, it shows that the last phase of	10	experience, your review of these company documents
11	their product strategy is obtaining clinical data,	11	and the peer-reviewed publications, do you have an
12	and that supports my opinion that the TVT-Secur	12	opinion whether or not a company should research
13	device was not adequately tested prior to launch.	13	products before they develop and launch products as
14	Q. Wait. Now, hold on a second. Let's	14	permanent implant devices for human use?
15	look at these phases really quickly, okay.	15	MR. SNELL: Object.
16	What was Phase 1 for Ethicon's product	16	BY THE WITNESS:
17	strategy concerning the TVT-Secur device?	17	A. Products should be researched prior to
18	A. Actively convert the obturator users,	18	launch for human use.
19	also approach the low hanging retropubic users.	19	BY MR. THORNBURGH:
20	Q. So, would Phase 1 occur after launch of	20	Q. Did Ethicon appropriately research the
21	the product?	21	TVT-Secur product before they launched it on to the
22	A. Yes.	22	market?
23	Q. What about Phase 2, would that be after	23	MR. SNELL: Object.
24	launch of the product?	24	BY THE WITNESS:
	Page 223		Page 225
1	A. Yes.	1	A. No, they did not. There was not
2	Q. And what was Phase 2?	2	appropriate testing prior to launch.
3	A. Convert the remaining of the obturator	3	BY MR. THORNBURGH:
4	users and actively convert all retropubic users.	4	Q. Because I got an objection, let me
5	Q. Now, was Phase 3 also after the launch	5 6	reask.
6	of the product?	7	Because do you have an opinion
7	A. Yes.		whether or not Ethicon appropriately researched its
8	Q. So, hold on a second.	8	product, the TVT-Secur, before they launched it?
9	Ethicon has, "Protect market share	9	A. Yes, I have an opinion.
10 11	through Key Opinion Leaders, KOLs, and clinical data." That was their third phase. Am I reading	11	MR. SNELL: Objection. BY MR. THORNBURGH:
12	•	12	Q. What's that opinion?
13	that correctly?	13	MR. SNELL: Same objection. Go ahead.
13 14	MR. SNELL: Objection; leading. BY THE WITNESS:	14	BY THE WITNESS:
14 15	A. Yes.	15	A. It was not appropriately researched or
16	A. Yes. BY MR. THORNBURGH:	16	A. It was not appropriately researched or tested prior to launch.
17	Q. Let me rephrase because I got an	17	BY MR. THORNBURGH:
18	objection.	18	Q. In your opinion is it ever appropriate
1.0	•	19	for companies such as Ethicon who are selling
	Phase 3 was to protect market share	20	patients permanent implantable medical devices to
19	through K() I condictional data is that somesative	∠∪	
19 20	through KOLs and clinical data, is that correct?	21	develop and market products before they conduct the
19 20 21	MR. SNELL: Leading.	21	develop and market products before they conduct the
19 20 21 22	MR. SNELL: Leading. BY THE WITNESS:	22	appropriate research?
19 20 21	MR. SNELL: Leading.	1	

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	Page 226		Page 228
1	A. No, that is never appropriate.	1	that had never been used before should dedicate
2	BY MR. THORNBURGH:	2	some of its budget pre-launch to testing their
3	Q. Is it appropriate for companies to put	3	products and conducting adequate testing of their
4	the D before the R	4	products in humans?
5	MR. SNELL: Object.	5	MR. SNELL: Object.
6	BY MR. THORNBURGH:	6	BY THE WITNESS:
7	Q in R & D?	7	A. Yes. The product should be adequately
8	MR. SNELL: Object: Leading as well.	8	tested prior to launch and adequate budget should
9	BY THE WITNESS:	9	be set aside to conduct testing prior to launch.
10	A. It is not appropriate to launch a	10	BY MR. THORNBURGH:
11	product without it being adequately tested.	11	Q. Do you have an opinion whether or not
12	BY MR. THORNBURGH:	12	medical device companies should budget more
13	Q. Do you have an opinion whether or not	13	money more money to conducting randomized
14	the conduct of Ethicon in developing this product	14	controlled trials or adequate testing than they do
15	strategy was appropriate?	15	in marketing?
16	MR. SNELL: Object.	16	MR. SNELL: Object.
17	BY THE WITNESS:	17	BY THE WITNESS:
18	A. It was not appropriate.	18	A. Yes.
19	BY MR. THORNBURGH:	19	BY MR. THORNBURGH:
20	Q. Do you have an opinion whether or not	20	Q. What's that opinion?
21	conducting business in this manner places women at	21	A. That they should allocate more money for
22	risk of suffering harm or injuries?	22	adequately testing a product prior to launch than
23	MR. SNELL: Object.	23	they should allocate towards marketing.
24	BY THE WITNESS:	24	Q. Have you reviewed any internal Ethicon
	Page 227		Page 229
1	A. Yes, it puts women at risk of harm and	1	documents that discuss a reason why randomized
2	injury.	2	controlled trials were not conducted by Ethicon?
3	BY MR. THORNBURGH:	3	MR. SNELL: Object; leading.
4	Q. Is there another slide you'd like to	4	BY THE WITNESS:
5	discuss with us?	5	A. Yes.
6	A. Yes. Pre-launch marketing budget for	6	BY MR. THORNBURGH:
7	2005.	7	Q. And what is your opinion as to why
8	Q. Try to find it, Doctor.	8	Ethicon chose not to conduct randomized controlled
9	And what is the significance of this	9	trials prior to launching the TVT-Secur product?
10	slide, Doctor?	10	MR. SNELL: Object.
11	A. Well, it supports my opinion that there	11	BY THE WITNESS:
12	was no clinical testing prior to launch of the	12	A. Budget constraints.
13	TVT-Secur.	13	BY MR. THORNBURGH:
14	Q. Now, let's look at this. It says,	14	Q. Based on your review of this slide, the
15	"Gynecare TVT-Secur Pre-Launch Marketing 2005	15	pre-launch marketing 2005 budget, with a total
16	Budget."	16	budget of 80 \$800 million, is there any
17	Did I read that correctly?	17	indication that Johnson & Johnson or Ethicon did
18	A. Yes.	18	not have enough money to conduct adequate testing?
19	Q. How much, according to this budget, did	19	MR. SNELL: Objection.
20	Ethicon budget for developing or for conducting	20	BY THE WITNESS:
21	randomized controlled trials?	21	A. That would not appear that way from that
22	A. Zero.	22	slide.
23	Q. Do you have an opinion whether or not a	23	BY MR. THORNBURGH:
24	company who is selling a new device and technique	24	Q. Are there any other slides you'd like to

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	Page 230		Page 232
1	discuss with respect to Exhibit P842?	1	make certain marketing claims that they wouldn't
2	A. Yes. It's called "Potential Marketing	2	prove until they conducted later clinical trials?
3	Claims."	3	MR. SNELL: Object and leading.
4	Q. And what, if anything, is relevant with	4	BY THE WITNESS:
5	this slide and how does it support your opinions?	5	A. That's what this document states.
6	A. This is a slide of what they will be	6	BY MR. THORNBURGH:
7	claiming as a TVT-Secur device. They would	7	Q. What does this document and the red and
8	wanted to claim that it had the same equivalence as	8	black font indicate to you and how does it support
9	the TVT. The data show that it was not equivalent	9	your opinions?
10	to the TVT.	10	MR. SNELL: Objection.
11	That the length was acceptable to all	11	BY THE WITNESS:
12	patients. The 8 centimeter length did not stay in	12	A. The red font is claims that would be
13	place in all patients and therefore the failure	13	later proven from either clinical data or clinical
14	rate was high.	14	experience. Therefore, that supports my opinion
15	They wanted to claim that laser-cut mesh	15	that the TVT-Secur was not adequately studied prior
16	was the same as the mechanical-cut mesh. However,	16	to launch.
17	the laser-cut mesh was found to be three times	17	
18	stiffer than mechanical-cut laser and stiffness	18	Q. Is it in your opinion, is it ever appropriate for a company to make marketing claims
19	leads to the harms that I've described previously.	19	that are unproven?
20	Q. What's your basis for that last	20	MR. SNELL: Objection.
21	statement, that the stiffness or rigidity of a mesh	21	BY THE WITNESS:
22	leads to harms that you've described previously?	22	A. That should not be done.
23	A. The medical literature.	23	BY MR. THORNBURGH:
24	MR. SNELL: Objection. I'm sorry. Object and	24	Q. And what can happen if companies like
	Daga 221		
	Page 231		Page 233
1	move to strike as non-responsive.	1	Page 233 Ethicon make unproven marketing claims?
1 2		1 2	
	move to strike as non-responsive.		Ethicon make unproven marketing claims?
2	move to strike as non-responsive. BY MR. THORNBURGH:	2	Ethicon make unproven marketing claims?  MR. SNELL: Objection.
2 3	move to strike as non-responsive.  BY MR. THORNBURGH:  Q. And we'll talk about those in greater	2 3	Ethicon make unproven marketing claims?  MR. SNELL: Objection. BY THE WITNESS:
2 3 4	move to strike as non-responsive.  BY MR. THORNBURGH:  Q. And we'll talk about those in greater detail. But what medical literature are you	2 3 4	Ethicon make unproven marketing claims?  MR. SNELL: Objection.  BY THE WITNESS:  A. That women will have the device
2 3 4 5	move to strike as non-responsive. BY MR. THORNBURGH: Q. And we'll talk about those in greater detail. But what medical literature are you referring to?	2 3 4 5	Ethicon make unproven marketing claims?  MR. SNELL: Objection.  BY THE WITNESS:  A. That women will have the device implanted that have design characteristics that
2 3 4 5 6	move to strike as non-responsive. BY MR. THORNBURGH: Q. And we'll talk about those in greater detail. But what medical literature are you referring to? A. The work done by the Feola group in	2 3 4 5 6	Ethicon make unproven marketing claims?  MR. SNELL: Objection.  BY THE WITNESS:  A. That women will have the device implanted that have design characteristics that make it either unreasonably unsafe or unreasonably
2 3 4 5 6 7	move to strike as non-responsive.  BY MR. THORNBURGH:  Q. And we'll talk about those in greater detail. But what medical literature are you referring to?  A. The work done by the Feola group in Pittsburgh. Excuse me. The Moalli group in	2 3 4 5 6 7	Ethicon make unproven marketing claims?  MR. SNELL: Objection. BY THE WITNESS:  A. That women will have the device implanted that have design characteristics that make it either unreasonably unsafe or unreasonably ineffective and will suffer harm from that.
2 3 4 5 6 7 8	move to strike as non-responsive.  BY MR. THORNBURGH:  Q. And we'll talk about those in greater detail. But what medical literature are you referring to?  A. The work done by the Feola group in Pittsburgh. Excuse me. The Moalli group in Pittsburgh.	2 3 4 5 6 7 8	Ethicon make unproven marketing claims?  MR. SNELL: Objection.  BY THE WITNESS:  A. That women will have the device implanted that have design characteristics that make it either unreasonably unsafe or unreasonably ineffective and will suffer harm from that.  BY MR. THORNBURGH:
2 3 4 5 6 7 8	move to strike as non-responsive.  BY MR. THORNBURGH:  Q. And we'll talk about those in greater detail. But what medical literature are you referring to?  A. The work done by the Feola group in Pittsburgh. Excuse me. The Moalli group in Pittsburgh.  Q. And this slide and I didn't mean to	2 3 4 5 6 7 8	Ethicon make unproven marketing claims?  MR. SNELL: Objection. BY THE WITNESS:  A. That women will have the device implanted that have design characteristics that make it either unreasonably unsafe or unreasonably ineffective and will suffer harm from that. BY MR. THORNBURGH:  Q. Is it are there any any more
2 3 4 5 6 7 8 9	move to strike as non-responsive.  BY MR. THORNBURGH:  Q. And we'll talk about those in greater detail. But what medical literature are you referring to?  A. The work done by the Feola group in Pittsburgh. Excuse me. The Moalli group in Pittsburgh.  Q. And this slide and I didn't mean to interrupt you. If you weren't done, keep on going,	2 3 4 5 6 7 8 9	Ethicon make unproven marketing claims?  MR. SNELL: Objection. BY THE WITNESS:  A. That women will have the device implanted that have design characteristics that make it either unreasonably unsafe or unreasonably ineffective and will suffer harm from that. BY MR. THORNBURGH:  Q. Is it are there any any more slides or data or information from this Exhibit
2 3 4 5 6 7 8 9 10	move to strike as non-responsive. BY MR. THORNBURGH: Q. And we'll talk about those in greater detail. But what medical literature are you referring to? A. The work done by the Feola group in Pittsburgh. Excuse me. The Moalli group in Pittsburgh. Q. And this slide and I didn't mean to interrupt you. If you weren't done, keep on going, Doctor.	2 3 4 5 6 7 8 9 10	Ethicon make unproven marketing claims?  MR. SNELL: Objection. BY THE WITNESS:  A. That women will have the device implanted that have design characteristics that make it either unreasonably unsafe or unreasonably ineffective and will suffer harm from that. BY MR. THORNBURGH:  Q. Is it are there any any more slides or data or information from this Exhibit No. 842 that support your opinions that you want to
2 3 4 5 6 7 8 9 10 11 12	move to strike as non-responsive.  BY MR. THORNBURGH:  Q. And we'll talk about those in greater detail. But what medical literature are you referring to?  A. The work done by the Feola group in Pittsburgh. Excuse me. The Moalli group in Pittsburgh.  Q. And this slide and I didn't mean to interrupt you. If you weren't done, keep on going, Doctor.  A. No. I'm finished with this.	2 3 4 5 6 7 8 9 10 11 12	Ethicon make unproven marketing claims?  MR. SNELL: Objection. BY THE WITNESS:  A. That women will have the device implanted that have design characteristics that make it either unreasonably unsafe or unreasonably ineffective and will suffer harm from that. BY MR. THORNBURGH:  Q. Is it are there any any more slides or data or information from this Exhibit No. 842 that support your opinions that you want to discuss today?
2 3 4 5 6 7 8 9 10 11 12 13	move to strike as non-responsive. BY MR. THORNBURGH: Q. And we'll talk about those in greater detail. But what medical literature are you referring to? A. The work done by the Feola group in Pittsburgh. Excuse me. The Moalli group in Pittsburgh. Q. And this slide and I didn't mean to interrupt you. If you weren't done, keep on going, Doctor. A. No. I'm finished with this. Q. And this particular slide shows	2 3 4 5 6 7 8 9 10 11 12 13	Ethicon make unproven marketing claims?  MR. SNELL: Objection. BY THE WITNESS:  A. That women will have the device implanted that have design characteristics that make it either unreasonably unsafe or unreasonably ineffective and will suffer harm from that. BY MR. THORNBURGH:  Q. Is it are there any any more slides or data or information from this Exhibit No. 842 that support your opinions that you want to discuss today?  A. No.
2 3 4 5 6 7 8 9 10 11 12 13 14	move to strike as non-responsive.  BY MR. THORNBURGH:  Q. And we'll talk about those in greater detail. But what medical literature are you referring to?  A. The work done by the Feola group in Pittsburgh. Excuse me. The Moalli group in Pittsburgh.  Q. And this slide and I didn't mean to interrupt you. If you weren't done, keep on going, Doctor.  A. No. I'm finished with this.  Q. And this particular slide shows potential marketing claims and there are a number	2 3 4 5 6 7 8 9 10 11 12 13 14	Ethicon make unproven marketing claims?  MR. SNELL: Objection. BY THE WITNESS:  A. That women will have the device implanted that have design characteristics that make it either unreasonably unsafe or unreasonably ineffective and will suffer harm from that. BY MR. THORNBURGH:  Q. Is it are there any any more slides or data or information from this Exhibit No. 842 that support your opinions that you want to discuss today?  A. No. Q. What's the next slide that you want to
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	Page 234		Page 236
1	BY MR. THORNBURGH:	1	Q. Is that a method used by the medical
2	Q. Let me ask it a better way.	2	community when determining what treatment options
3	Is it unreasonable for medical doctors	3	would be appropriate for their patients, one of the
4	to rely on the marketing claims made by medical	4	methods?
5	device companies like Ethicon who are promoting	5	MR. SNELL: Objection.
6	medical devices for the permanent implantation into	6	BY THE WITNESS:
7	patients?	7	A. Yes.
8	MR. SNELL: Objection.	8	BY MR. THORNBURGH:
9	BY MR. THORNBURGH:	9	Q. And is it important do you have an
10	Q. Is it unreasonable to rely on company	10	opinion whether or not it's important that doctors
11	representations about their devices?	11	are provided with the complete and accurate
12	MR. SNELL: Same.	12	information concerning the risks as well as the
13	BY THE WITNESS:	13	complete and accurate information concerning
14	A. It is not unreasonable to rely on claims	14	benefits?
15	that are made by the company.	15	A. Yes.
16	BY MR. THORNBURGH:	16	MR. SNELL: Objection.
17	Q. Do you have an opinion whether or not	17	BY MR. THORNBURGH:
18	medical device companies like Ethicon and	18	Q. If if medical device companies like
19	Johnson & Johnson should not only disclose the	19	Ethicon and Johnson & Johnson do not provide
20	benefits of their products, but also safety or	20	complete and accurate information concerning both
21	efficacy problems with their products?	21	the risks and the benefits of medical devices that
22	A. Yes.	22	they're promoting, can that impact patient safety?
23	Q. And why is that important?	23	MR. SNELL: Objection.
24	A. It is important so that doctors know all	24	BY THE WITNESS:
	Daga 225		Dago 227
1	Page 235	1	Page 237
1	of the risks associated with the device so the	1 2	A. Yes. BY MR. THORNBURGH:
2 3	doctor can make a decision whether or not they will	3	Q. Can that impact the decision-making
4	use that device in their patients so they can give	4	process of physicians?
5	that information to the patients so the patient can		
6	ultimately make an informed decision about their treatment.	5 6	MR. SNELL: Object. BY THE WITNESS:
7		7	A. Yes.
8	Q. How do doctors make a decision about treatment options for their patients?	8	BY MR. THORNBURGH:
9	MR. SNELL: Objection.	9	Q. How so?
10	BY THE WITNESS:	10	A. If all the information regarding the
11		11	characteristics of a device that make it
12	A. Based on information that is provided by	12	unreasonably unsafe or unreasonably ineffective are
13	the manufacturer, what's in the literature, and from their clinical experience.	13	not shared with doctors, doctors cannot make an
14	BY MR. THORNBURGH:	14	accurate risk/benefit analysis and have a proper
15	Q. I've heard the phrase before	15	risk discussion with their patients.
16	"risk/benefit assessment." Have you heard am I	16	Q. Okay. And let's discuss Exhibit P1352.
17	using that phrase correctly?	17	Did you review and rely on this document in
18	A. Yes.	18	rendering your opinions in this case?
19	Q. Doctor, what is a risk/benefit	19	A. Yes.
20	assessment?	20	Q. And I think you testified earlier that
21	A. It is an assessment that is made where	21	you had seen this document before you were retained
22	the risks associated with an individual device,	22	as an expert in this litigation?
		23	A. Yes.
2.5			
23 24	procedure or treatment is weighed against the utility or benefits to the patient.	24	Q. Is it fair to say that of all the

60 (Pages 234 to 237)

	Page 238		Page 240
1	documents we've looked at so far, internal company	1	MR. SNELL: Object.
2	documents, other than this document and the	2	BY THE WITNESS:
3	TVT-Secur IFU that we looked at earlier, were any	3	A. Yes.
4	of those other documents disclosed to you or to the	4	BY MR. THORNBURGH:
5	medical community?	5	Q. Do you agree or disagree with
6	MR. SNELL: Objection.	6	Dr. Arnaud?
7	BY THE WITNESS:	7	A. I
8	A. Not that I recall.	8	MR. SNELL: Same.
9	BY MR. THORNBURGH:	9	BY THE WITNESS:
10	Q. Okay. And what about Exhibit 1352 is	10	A. I agree with Dr. Arnaud that it is not a
11	relevant to your opinions? And if you could	11	revolution.
12	explain briefly how this information or what	12	BY MR. THORNBURGH:
13	information you rely on to support those opinions.	13	Q. What's the next part of Exhibit P1352
14	A. I rely on relied on the entire	14	that is relevant and that you rely on for your
15	document to support my opinions that the TVT-Secur	15	opinions?
16	data there was no data on the TVT-Secur at the	16	A. The statement that it is less
17	time of launch.	17	complicated.
18	Therefore, these brochures that talk	18	Q. And how does that support your opinion?
19	about a 97% overall success rate, that it had	19	A. This statements that the TVT-Secur is
20	been that there was a low complication rate and	20	designed to reduce the number of procedural steps.
21	that it had been in over a million used in over	21	From the cadaver studies and the design validation,
22	a million women worldwide and that there is	22	it was found to be more complicated to insert with
23	seven-year proven efficacy, is not data that is	23	more difficulty inserting than the prior TVT
24	applicable to the TVT-Secur.	24	devices.
	Page 239		Page 241
1	Q. Okay.	1	Q. So, is this statement by Ethicon that
2	<ul><li>Q. Okay.</li><li>MR. SNELL: Objection. Move to strike.</li></ul>	2	Q. So, is this statement by Ethicon that the TVT-Secur was less complicated true or
2	<ul><li>Q. Okay.</li><li>MR. SNELL: Objection. Move to strike.</li><li>Non-responsive.</li></ul>	2 3	Q. So, is this statement by Ethicon that the TVT-Secur was less complicated true or incorrect?
2 3 4	<ul><li>Q. Okay.</li><li>MR. SNELL: Objection. Move to strike.</li><li>Non-responsive.</li><li>BY MR. THORNBURGH:</li></ul>	2 3 4	Q. So, is this statement by Ethicon that the TVT-Secur was less complicated true or incorrect?  MR. SNELL: Object.
2 3 4 5	<ul><li>Q. Okay.</li><li>MR. SNELL: Objection. Move to strike.</li><li>Non-responsive.</li><li>BY MR. THORNBURGH:</li><li>Q. Okay. And this document, the very</li></ul>	2 3 4 5	Q. So, is this statement by Ethicon that the TVT-Secur was less complicated true or incorrect?  MR. SNELL: Object. BY THE WITNESS:
2 3 4 5 6	Q. Okay. MR. SNELL: Objection. Move to strike. Non-responsive. BY MR. THORNBURGH: Q. Okay. And this document, the very first the title of this promotional piece says	2 3 4 5 6	Q. So, is this statement by Ethicon that the TVT-Secur was less complicated true or incorrect?  MR. SNELL: Object. BY THE WITNESS:  A. Incorrect.
2 3 4 5	Q. Okay. MR. SNELL: Objection. Move to strike. Non-responsive. BY MR. THORNBURGH: Q. Okay. And this document, the very first the title of this promotional piece says "No bigger than your palm. No less than a	2 3 4 5	Q. So, is this statement by Ethicon that the TVT-Secur was less complicated true or incorrect?  MR. SNELL: Object. BY THE WITNESS:  A. Incorrect. BY MR. THORNBURGH:
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2 3 4 5 6 7 8 9 10 11 12 13	Q. Okay. MR. SNELL: Objection. Move to strike. Non-responsive. BY MR. THORNBURGH: Q. Okay. And this document, the very first the title of this promotional piece says "No bigger than your palm. No less than a revolution." Do you see that? A. Yes. Q. Did you read the deposition testimony of Axel Arnaud? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13	Q. So, is this statement by Ethicon that the TVT-Secur was less complicated true or incorrect?  MR. SNELL: Object. BY THE WITNESS:  A. Incorrect. BY MR. THORNBURGH:  Q. And what's the support for that opinion?  A. The design validation which showed that it was much more complicated to put in.  Q. If we look at strike that.  What is the next relevant information you'd like to discuss?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. Okay. MR. SNELL: Objection. Move to strike. Non-responsive. BY MR. THORNBURGH: Q. Okay. And this document, the very first the title of this promotional piece says "No bigger than your palm. No less than a revolution." Do you see that? A. Yes. Q. Did you read the deposition testimony of Axel Arnaud? A. Yes. Q. Do you know whether or not based on your review of Axel Arnaud's testimony and before we	2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. So, is this statement by Ethicon that the TVT-Secur was less complicated true or incorrect?  MR. SNELL: Object. BY THE WITNESS:  A. Incorrect. BY MR. THORNBURGH:  Q. And what's the support for that opinion?  A. The design validation which showed that it was much more complicated to put in.  Q. If we look at strike that.  What is the next relevant information you'd like to discuss?  A. The next page, the "Novel Instrument Design, Stable." The absorbable fleece tips
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. Okay. MR. SNELL: Objection. Move to strike. Non-responsive. BY MR. THORNBURGH: Q. Okay. And this document, the very first the title of this promotional piece says "No bigger than your palm. No less than a revolution." Do you see that? A. Yes. Q. Did you read the deposition testimony of Axel Arnaud? A. Yes. Q. Do you know whether or not based on your review of Axel Arnaud's testimony and before we get there. So, strike the last question.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. So, is this statement by Ethicon that the TVT-Secur was less complicated true or incorrect?  MR. SNELL: Object. BY THE WITNESS:  A. Incorrect. BY MR. THORNBURGH:  Q. And what's the support for that opinion?  A. The design validation which showed that it was much more complicated to put in.  Q. If we look at strike that.  What is the next relevant information you'd like to discuss?  A. The next page, the "Novel Instrument Design, Stable." The absorbable fleece tips provide mechanical fixation until tissue ingrowth
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3 BY THE WITNESS: 4 A. Incorrect. 5 BY MR, THORNBURGH: 6 Q. Do you have an opinion whether or not it would be a misrepresentation for Ethicon to represent to physicians that the TVT-Secur was secure and would stay in place? 10 MR, SNELL: Objection. 11 BY THE WITNESS: 11 BY MR, THORNBURGH: 12 A. I do have an opinion. 13 BY MR, THORNBURGH: 14 Q. What shat opinion? 15 A. That that would be a misrepresentation. 16 Q. And by - by marketing this product and naming it the TVT-Secur, is that — do you have an opinion whether or not the name that Ethicon gave it was a misrepresentation? 19 it was a misrepresentation? 20 MR, SNELL: Objection. 21 BY THE WITNESS: 22 A. Yes, I have an opinion. 23 BY MR, THORNBURGH: 24 Q. What's that opinion? 25 BY MR, THORNBURGH: 26 BY MR, THORNBURGH: 27 A. It was a misrepresentation. 28 BY MR, THORNBURGH: 29 Gentlemen of the jury. 20 Man synell: Same. 30 MR, SNELL: Same. 41 BY THE WITNESS: 42 A. It was a misrepresentation. 43 BY THE WITNESS: 44 BY THE WITNESS: 45 A. The literature. 46 BY MR, THORNBURGH: 47 Q. Did Ethicon know or should they have known based on your review of the internal company documents by 2006 when they launched this product procedure? 48 BY THE WITNESS: 49 A. Yes. 49 C. Mad what were you showing the ladies and should be placed on a midurethral sling during the implantation. 40 Q. And what's the basis for that opinion? 41 A. It was a misrepresentation. 42 Q. And what's the basis for that opinion? 43 MR, SNELL: Same. 44 BY THE WITNESS: 45 A. The literature. 46 BY MR, THORNBURGH: 47 Q. Did Ethicon know or should they have known based on your review of the internal company documents by 2006 when they launched this product procedure? 40 Q. The next - what's the mext as a more complicated procedure? 41 A. Yes. 41 A. Yes. 42 Q. Mad what's the basis for that opinion? 43 MR, SNELL: Objection. 44 DY MR, SNELL: Objection. 45 BY MR, THORNBURGH: 46 DY MR, SNELL: Objection. 47 A. It says. Tension-free support for incontinence? 48 BY MR, THORNBURGH: 49 Q. Did Ethicon know before they		Page 242		Page 244
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5 BY MR. THORNBURGH: 6 Q. Do you have an opinion whether or not it 7 would be a misrepresentation for Ethicon to 8 represent to physicians that the TVT-Secur was 9 secure and would stay in place? 9 MR. SNELL: Objection. 10 MR. SNELL: Objection. 11 BY THE WITNESS: 12 A. I do have an opinion. 13 BY MR. THORNBURGH: 14 Q. What's that opinion? 15 A. That that would be a misrepresentation. 16 Q. And by — by marketing this product and 17 naming it the TVT-Secur, is that — do you have an 18 opinion whether or not the name that Ethicon gave 19 it was a misrepresentation? 10 BY MR. SNELL: Objection. 11 BY THE WITNESS: 12 A. Yes. The five-week data on 31 patie 12 which showed a failure rate of 30%. 13 BY MR. THORNBURGH: 14 Q. What's that opinion? 15 A. That that would be a misrepresentation. 16 Q. And by — by marketing this product and 17 naming it the TVT-Secur, is that — do you have an 18 opinion whether or not the name that Ethicon gave 19 it was a misrepresentation? 20 MR. SNELL: Objection. 21 BY THE WITNESS: 22 A. Yes. I have an opinion. 23 BY MR. THORNBURGH: 24 Q. What's that opinion? 25 A. The literature. 26 BY MR. THORNBURGH: 27 Q. Did Ethicon know or should they have 28 known based on your review of the internal company 29 documents by 2006 when they launched this product 20 that the TVT-Secur was a more complicated 21 procedure? 22 MR. SNELL: Objection. 23 BY THE WITNESS: 4 A. The literature. 5 Q. And what were you showing the ladies 29 gentlemen of the jury. 4 A. It says, "Tension-free support for 20 incontinence." 4 BY MR. THORNBURGH: 5 Q. Did Ethicon know before they launched 6 Q. Than the TVT-O or TVT Retropubic? 7 A. Yes. 8 Q. Did Ethicon know before they launched 10 that the TVT-Secur was a more complicated 11 procedure? 12 MR. SNELL: Objection. 13 BY MR. THORNBURGH: 14 BY MR. THORNBURGH: 15 BY MR. THORNBURGH: 16 Q. Than the TVT-O or TVT Retropubic? 17 A. Yes. 18 Q. Did Ethicon know before they launched 19 the TVT-Secur in September of 2006 that the mesh	3	BY THE WITNESS:	3	studies.
6 Q. Do you have an opinion whether or not it would be a misrepresentation for Ethicon to respect to physicians that the TVT-Secur was secure and would stay in place? 9 MR. SNELL: Objection. 10 MR. SNELL: Objection. 11 BY THE WITNESS: 11 BY MR. THORNBURGH: 12 A. It was a misrepresentation. 13 BY MR. THORNBURGH: 14 Q. What's that opinion? 15 A. That that would be a misrepresentation. 16 Q. And by - by marketing this product and naming it the TVT-Secur, is thatdo you have an opinion whether or not the name that Ethicon gave it was a misrepresentation? 18 BY THE WITNESS: 19 A. Yes, I have an opinion. 19 What's that opinion? 20 MR. SNELL: Objection. 21 BY THE WITNESS: 22 A. Yes, I have an opinion. 23 BY MR. THORNBURGH: 24 Q. What's that opinion? 25 A. The iterature. 26 BY MR. THORNBURGH: 37 Q. Did Ethicon know or should they have known based on your review of the internal company of documents by 2006 when they launched this product that the TVT-Secur was a more complicated procedure? 10 MR. SNELL: Objection. 11 BY MR. SNELL: Objection. 12 MR. SNELL: Objection. 13 BY MR. THORNBURGH: 14 A. It was a misrepresentation. 15 A. The literature. 16 BY MR. THORNBURGH: 17 Q. Did Ethicon know before they launched the total company of documents by 2006 when they launched the total company of documents by 2006 when they launched the total company of documents by 2006 when they launched the total company of documents by 2006 when they launched the total company of documents by 2006 when they launched the total company of documents by 2006 when they launched the total company of documents by 2006 when they launched the total company of documents by 2006 when they launched the total company of documents by 2006 when they launched the total company of documents by 2006 when they launched the total company of documents by 2006 when they launched the total company of documents by 2006 when they launched the total company of the	4	A. Incorrect.	4	Q. And did Ethicon conduct any human
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Page 243  Page 243  Page 243  Page 243  A. It was a misrepresentation.  Q. And what's the basis for that opinion?  BY THE WITNESS:  A. The literature.  BY MR. THORNBURGH:  Q. Did Ethicon know or should they have  known based on your review of the internal company odocuments by 2006 when they launched this product that the TVT-Secur was a more complicated  MR. SNELL: Objection.  MR. SNELL: Objection.  BY MR. THORNBURGH:  Q. Did Ethicon know or should they have  Rows it an accurate statement or representation that the Gynecare TVT-Secur sy as a more complicated  MR. SNELL: Objection.  A. Yes.  MR. A. Inaccurate.  BY MR. THORNBURGH:  Q. And what's the basis for that opinion?  A. Yes.  MR. Yes.  MR. Thornburgh:  Q. And what's the basis for that opinion?  A. The internal documents and the literature.  Q. And did Ethicon know before they launched the TVT-Secur in September of 2006 that the mesh	22	A. Yes, I have an opinion.	22	Q. And if we look at the TVT-Secur box
Page 243  1 A. It was a misrepresentation. 2 Q. And what's the basis for that opinion? 3 MR. SNELL: Same. 4 BY THE WITNESS: 5 A. The literature. 6 BY MR. THORNBURGH: 7 Q. Did Ethicon know or should they have 8 known based on your review of the internal company 9 documents by 2006 when they launched this product 10 that the TVT-Secur was a more complicated 11 gentlemen of the jury. 12 THE VIDEOGRAPHER: Let me focus. He of the jury in the product of the internal company 13 Okay. I got it. 14 BY MR. THORNBURGH: 5 Q. And what were you showing the ladies gentlemen of the jury? 7 A. It says, "Tension-free support for incontinence." 9 Q. Was it an accurate statement or representation that the Gynecare TVT-Secur sy was tension-free support for incontinence? 10 WR. SNELL: Objection. 11 BY THE WITNESS: 12 BY THE WITNESS: 13 BY THE WITNESS: 14 A. Yes. 15 BY MR. THORNBURGH: 16 Q. Than the TVT-O or TVT Retropubic? 17 A. Yes. 18 Q. Did Ethicon know before they launched 19 the TVT-Secur in September of 2006 that the mesh 19 Q. And did Ethicon know before they	23	BY MR. THORNBURGH:	23	really quick, the box that the TVT-Secur came in.
1 A. It was a misrepresentation. 2 Q. And what's the basis for that opinion? 3 MR. SNELL: Same. 4 BY THE WITNESS: 5 A. The literature. 6 BY MR. THORNBURGH: 7 Q. Did Ethicon know or should they have 8 known based on your review of the internal company 9 documents by 2006 when they launched this product 10 that the TVT-Secur was a more complicated 11 gentlemen of the jury. 12 THE VIDEOGRAPHER: Let me focus. He Okay. I got it. 13 BY THE WITNESS: 4 BY MR. THORNBURGH: 5 Q. And what were you showing the ladies gentlemen of the jury? 7 A. It says, "Tension-free support for incontinence." 9 Q. Was it an accurate statement or representation that the Gynecare TVT-Secur sy was tension-free support for incontinence? 10 The WITNESS: 11 Was tension-free support for incontinence? 12 MR. SNELL: Objection. 13 BY THE WITNESS: 14 A. Yes. 15 BY MR. THORNBURGH: 16 Q. Than the TVT-O or TVT Retropubic? 17 A. Yes. 18 Q. Did Ethicon know before they launched 19 the TVT-Secur in September of 2006 that the mesh 19 Q. And did Ethicon know before they	24	Q. What's that opinion?	24	Hold that up for the ladies and
Q. And what's the basis for that opinion?  MR. SNELL: Same.  BY THE WITNESS:  A. The literature.  BY MR. THORNBURGH:  Q. Did Ethicon know or should they have  known based on your review of the internal company  documents by 2006 when they launched this product  that the TVT-Secur was a more complicated  THE VIDEOGRAPHER: Let me focus. He Was I got it.  BY MR. THORNBURGH:  Q. And what were you showing the ladies gentlemen of the jury?  A. It says, "Tension-free support for incontinence."  Q. Was it an accurate statement or representation that the Gynecare TVT-Secur sy was tension-free support for incontinence?  MR. SNELL: Objection.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:  Q. Than the TVT-O or TVT Retropubic?  A. Yes.  PY MR. THORNBURGH:  Q. And what's the basis for that opinion?  A. Yes.  PY MR. THORNBURGH:  Q. And what's the basis for that opinion?  A. The internal documents and the literature.  PY MR. SNELL: On the TVT-Secur in September of 2006 that the mesh  PY MR. And did Ethicon know before they		Page 243		Page 245
Q. And what's the basis for that opinion?  MR. SNELL: Same.  BY THE WITNESS:  A. The literature.  BY MR. THORNBURGH:  Q. Did Ethicon know or should they have  known based on your review of the internal company  documents by 2006 when they launched this product  that the TVT-Secur was a more complicated  THE VIDEOGRAPHER: Let me focus. He are the focus in the focus. He are the focus in the focus. He are the focus in the focus. He are the focus. He are the focus. He are the focus in the focus in the focus in the focus. He are the focus in the	1	A. It was a misrepresentation.	1	gentlemen of the jury.
MR. SNELL: Same.  4 BY THE WITNESS:  5 A. The literature.  6 BY MR. THORNBURGH:  7 Q. Did Ethicon know or should they have  8 known based on your review of the internal company  9 documents by 2006 when they launched this product  10 that the TVT-Secur was a more complicated  11 procedure?  12 MR. SNELL: Objection.  13 BY THE WITNESS:  14 A. Yes.  15 BY MR. THORNBURGH:  16 Q. Than the TVT-O or TVT Retropubic?  17 A. Yes.  18 Q. Did Ethicon know before they launched  19 Q. And what were you showing the ladies gentlemen of the jury?  A. It says, "Tension-free support for incontinence."  9 Q. Was it an accurate statement or representation that the Gynecare TVT-Secur sy was tension-free support for incontinence?  10 MR. SNELL: Object.  11 BY THE WITNESS:  12 A. Inaccurate.  13 BY THE WITNESS:  14 A. Inaccurate.  15 BY MR. THORNBURGH:  16 Q. And what's the basis for that opinion?  17 A. Yes.  18 Q. Did Ethicon know before they launched  19 the TVT-Secur in September of 2006 that the mesh  19 Q. And did Ethicon know before they	2		2	THE VIDEOGRAPHER: Let me focus. Hold on.
A. The literature.  BY MR. THORNBURGH:  Q. Did Ethicon know or should they have  known based on your review of the internal company  documents by 2006 when they launched this product  that the TVT-Secur was a more complicated  procedure?  MR. SNELL: Objection.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:  Q. Than the TVT-O or TVT Retropubic?  A. Yes.  PY MR. THORNBURGH:  Q. Did Ethicon know before they launched  the TVT-Secur in September of 2006 that the mesh  D. And what were you showing the ladies gentlemen of the jury?  A. It says, "Tension-free support for incontinence."  Q. Was it an accurate statement or representation that the Gynecare TVT-Secur sy was tension-free support for incontinence?  MR. SNELL: Object.  BY MR. SNELL: Object.  BY THE WITNESS:  A. Inaccurate.  BY MR. THORNBURGH:  Q. And what's the basis for that opinion?  A. The internal documents and the literature.  P. And did Ethicon know before they	3		3	Okay. I got it.
6 BY MR. THORNBURGH: 7 Q. Did Ethicon know or should they have 8 known based on your review of the internal company 9 documents by 2006 when they launched this product 10 that the TVT-Secur was a more complicated 10 procedure? 11 was tension-free support for incontinence? 12 MR. SNELL: Objection. 13 BY THE WITNESS: 14 A. Yes. 15 BY MR. THORNBURGH: 16 Q. Than the TVT-O or TVT Retropubic? 17 A. Yes. 18 Q. Did Ethicon know before they launched 19 Q. And did Ethicon know before they 19 Q. Was it an accurate statement or 10 representation that the Gynecare TVT-Secur sy 11 was tension-free support for incontinence? 12 MR. SNELL: Object. 13 BY THE WITNESS: 14 A. Inaccurate. 15 BY MR. THORNBURGH: 16 Q. And what's the basis for that opinion? 17 A. Yes. 18 Q. Did Ethicon know before they launched 19 U. And did Ethicon know before they	4		4	-
Q. Did Ethicon know or should they have known based on your review of the internal company documents by 2006 when they launched this product that the TVT-Secur was a more complicated procedure?  MR. SNELL: Objection.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:  Q. Than the TVT-O or TVT Retropubic?  A. Yes.  Q. Was it an accurate statement or representation that the Gynecare TVT-Secur sy was tension-free support for incontinence?  MR. SNELL: Object.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:  Q. And what's the basis for that opinion?  A. Yes.  Q. And what's the basis for that opinion?  A. The internal documents and the literature.  Which is a paper of the support for incontinence?  A. It says, "Tension-free support for incontinence."  A. It says, "Tension-free support for incontinence."  A. It says, "Tension-free support for incontinence."  Paper of the Gynecare TVT-Secur sy was tension-free support for incontinence?  MR. SNELL: Object.  BY THE WITNESS:  A. Inaccurate.  BY MR. THORNBURGH:  Q. And what's the basis for that opinion?  A. The internal documents and the literature.  Q. And did Ethicon know before they	5	A. The literature.	5	Q. And what were you showing the ladies and
known based on your review of the internal company documents by 2006 when they launched this product that the TVT-Secur was a more complicated procedure?  MR. SNELL: Objection.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:  Q. Was it an accurate statement or representation that the Gynecare TVT-Secur sy was tension-free support for incontinence?  MR. SNELL: Object.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:  Q. Than the TVT-O or TVT Retropubic?  A. Yes.  Q. And what's the basis for that opinion?  A. Yes.  Q. Did Ethicon know before they launched this product the TVT-Secur in September of 2006 that the mesh  Representation that the Gynecare TVT-Secur sy and constant the Gynecare TVT-Secur sy representation that the Gynecare TVT-Secur sy and constant the Gynecare TVT-Secur sy and constan	6	BY MR. THORNBURGH:	6	gentlemen of the jury?
documents by 2006 when they launched this product that the TVT-Secur was a more complicated procedure?  MR. SNELL: Objection.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:  Q. Than the TVT-O or TVT Retropubic?  A. Yes.  Q. Was it an accurate statement or representation that the Gynecare TVT-Secur sy was tension-free support for incontinence?  MR. SNELL: Object.  BY THE WITNESS:  A. Inaccurate.  BY MR. THORNBURGH:  Q. And what's the basis for that opinion?  A. Yes.  Q. Did Ethicon know before they launched the TVT-Secur in September of 2006 that the mesh  Q. And did Ethicon know before they  Q. And did Ethicon know before they	7	Q. Did Ethicon know or should they have	7	A. It says, "Tension-free support for
that the TVT-Secur was a more complicated  10 representation that the Gynecare TVT-Secur sy 11 procedure?  12 MR. SNELL: Objection.  13 BY THE WITNESS:  14 A. Yes.  15 BY MR. THORNBURGH:  16 Q. Than the TVT-O or TVT Retropubic?  17 A. Yes.  18 Q. Did Ethicon know before they launched  19 the TVT-Secur was a more complicated  10 representation that the Gynecare TVT-Secur sy 11 was tension-free support for incontinence?  MR. SNELL: Object.  12 MR. SNELL: Object.  13 BY THE WITNESS:  14 A. Inaccurate.  15 BY MR. THORNBURGH:  16 Q. And what's the basis for that opinion?  17 A. Yes.  18 literature.  19 Q. And did Ethicon know before they	8	known based on your review of the internal company	8	incontinence."
procedure?  MR. SNELL: Objection.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:  Q. Than the TVT-O or TVT Retropubic?  A. Yes.  Q. Did Ethicon know before they launched  the TVT-Secur in September of 2006 that the mesh  11 was tension-free support for incontinence?  MR. SNELL: Object.  BY MR. SNELL: Object.  BY THE WITNESS:  A. Inaccurate.  BY MR. THORNBURGH:  Q. And what's the basis for that opinion?  A. The internal documents and the  literature.  Q. And did Ethicon know before they	9	documents by 2006 when they launched this product	9	Q. Was it an accurate statement or
MR. SNELL: Objection.  12 MR. SNELL: Object.  13 BY THE WITNESS:  14 A. Yes.  15 BY MR. THORNBURGH:  16 Q. Than the TVT-O or TVT Retropubic?  17 A. Yes.  18 Q. Did Ethicon know before they launched  19 the TVT-Secur in September of 2006 that the mesh  19 MR. SNELL: Object.  10 MR. SNELL: Object.  11 BY THE WITNESS:  12 MR. SNELL: Object.  13 BY THE WITNESS:  14 A. Inaccurate.  15 BY MR. THORNBURGH:  16 Q. And what's the basis for that opinion?  17 A. The internal documents and the  18 literature.  19 Q. And did Ethicon know before they	10	that the TVT-Secur was a more complicated	10	representation that the Gynecare TVT-Secur system
13 BY THE WITNESS: 14 A. Yes. 15 BY MR. THORNBURGH: 16 Q. Than the TVT-O or TVT Retropubic? 17 A. Yes. 18 Q. Did Ethicon know before they launched 19 the TVT-Secur in September of 2006 that the mesh 10 BY THE WITNESS: 14 A. Inaccurate. 15 BY MR. THORNBURGH: 16 Q. And what's the basis for that opinion? 17 A. The internal documents and the literature. 18 Q. And did Ethicon know before they	11		11	was tension-free support for incontinence?
14 A. Yes.  15 BY MR. THORNBURGH:  16 Q. Than the TVT-O or TVT Retropubic?  17 A. Yes.  18 Q. Did Ethicon know before they launched  19 the TVT-Secur in September of 2006 that the mesh  19 A. Yes.  10 A. Inaccurate.  15 BY MR. THORNBURGH:  16 Q. And what's the basis for that opinion?  17 A. The internal documents and the literature.  18 literature.  19 Q. And did Ethicon know before they	12	MR. SNELL: Objection.	12	MR. SNELL: Object.
15 BY MR. THORNBURGH: 16 Q. Than the TVT-O or TVT Retropubic? 17 A. Yes. 18 Q. Did Ethicon know before they launched 19 the TVT-Secur in September of 2006 that the mesh 19 BY MR. THORNBURGH: 10 Q. And what's the basis for that opinion? 11 A. The internal documents and the literature. 12 Q. And did Ethicon know before they	13	BY THE WITNESS:	13	BY THE WITNESS:
Q. Than the TVT-O or TVT Retropubic?  16 Q. And what's the basis for that opinion?  17 A. Yes.  18 Q. Did Ethicon know before they launched  18 literature.  19 the TVT-Secur in September of 2006 that the mesh  19 Q. And did Ethicon know before they	14	A. Yes.	14	A. Inaccurate.
17 A. Yes.  18 Q. Did Ethicon know before they launched 19 the TVT-Secur in September of 2006 that the mesh 19 A. The internal documents and the 18 literature. 19 Q. And did Ethicon know before they	15	BY MR. THORNBURGH:	15	BY MR. THORNBURGH:
18 Q. Did Ethicon know before they launched 18 literature.  19 the TVT-Secur in September of 2006 that the mesh 19 Q. And did Ethicon know before they	16	Q. Than the TVT-O or TVT Retropubic?	16	Q. And what's the basis for that opinion?
19 the TVT-Secur in September of 2006 that the mesh 19 Q. And did Ethicon know before they	17	A. Yes.	17	A. The internal documents and the
	18	Q. Did Ethicon know before they launched	18	literature.
20 would not stay in place? 20 marketed and sold this product that it would be	19	the TVT-Secur in September of 2006 that the mesh	19	Q. And did Ethicon know before they
	20	would not stay in place?	20	marketed and sold this product that it would be a
21 MR. SNELL: Objection. 21 misrepresentation to claim that the Gynecare	21	MR. SNELL: Objection.	21	misrepresentation to claim that the Gynecare
22 BY THE WITNESS: 22 TVT-Secur system was tension-free support for	22	BY THE WITNESS:	22	TVT-Secur system was tension-free support for
23 A. Yes. 23 incontinence?	23	A. Yes.	23	incontinence?
24 BY MR. THORNBURGH: 24 MR. SNELL: Object.	24	BY MR. THORNBURGH:	24	MR. SNELL: Object.

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3 BY MR. THORNBURGH: 3 that that a moment	GH: oked at some claims
3 BY MR. THORNBURGH: 3 that that a moment	oked at some claims
3 BY MR. THORNBURGH: 3 that that a moment	
4 Q. And what's the next page you'd like to 4 Exhibit 842 for some c	claims that Ethicon would use
Troping and the second	cur product. Do you recall
6 A. The "Materials, Dependable, Reliable." 6 that?	our producti Do you recuir
7 Q. Do you have an opinion whether or not 7 A. Yes.	
	first go to a side-by-side
	s data that is reflected in
	of Exhibit 1352 and compare
•	nicon wanted to make with
12 A. Well, the Prolene mesh in the short 12 respect to the TVT-Sec	
13 length with laser cutting had never been used  13 MR. SNELL: Object  13 MR. SNELL:	
	GH: And what slide is that again,
15 dependable because it had not been studied in 15 Tom? Could you just p	=
*	=
1	It's the last one. So, it's GH: The last slide of
	JH: The last slide of
======================================	SI' le 40 mars 41 ef de
· I	Slide 40, page 41 of the
20 that they had was on 31 women for five weeks. So, 20 document.	.CH
21 to be able to say that the short mesh with 21 BY MR. THORNBURG	
* * *	, again, we looked at this
23 reliable, the only human data was on 31 women for 23 earlier, but it says red v	would be "Later from
24 five weeks. 24 clinicals."	
Page 247	Page 249
1 Q. And did the human data on 31 women for 1 Do you see that	t?
2 five weeks, did that demonstrate or prove that the 2 A. Yes.	
	that Ethicon was going to
<u> </u>	e TVT-Secur says, or one of the
	efficacy to TVT or TVT-O."
6 A. No, there is a failure rate of 30%. 6 Do you see that	
7 BY MR. THORNBURGH: 7 MR. SNELL: Obje	
8 Q. Did it prove or demonstrate that the 8 BY THE WITNESS:	
9 TVT-Secur would be reliable? 9 A. Yes.	
10 A. No, there was a 60% complication rate. 10 BY MR. THORNBUR	RGH:
	icon's own internal document
	rketing claims, was that claim
13 Nonresponsive. Go ahead. 13 proven or unproven?	,
14 BY MR. THORNBURGH: 14 MR. SNELL: Objection of the control of th	ection.
15 Q. What is the next is there any other 15 BY THE WITNESS:	
16 information you'd like to discuss from 16 A. Unproven.	
17 Exhibit P1352? 17 BY MR. THORNBUR	RGH:
	ite that, if we go and
	the data that was being
	P1352, what was Ethicon
The statements from key Hinton employees noting that 1 /11 infovided to doctors in	1 1 1 2 2 2, What was Ellicon
	rians who were considering
21 the seven-year data would not be reliably 21 representing to physic	cians who were considering
the seven-year data would not be reliably 21 representing to physic translatable to the TVT-Secur. 22 whether or not to imple	cians who were considering lant the TVT-Secur permanently
21 the seven-year data would not be reliably 21 representing to physic	

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	Page 250		Page 252
1	MR. SNELL: Objection.	1	marketing piece that this was an unproven claim?
2	BY THE WITNESS:	2	MR. SNELL: Objection.
3	A. That the overall success rate was 97%.	3	BY THE WITNESS:
4	BY MR. THORNBURGH:	4	A. No, they did not.
5	Q. Were they suggesting that the success	5	BY MR. THORNBURGH:
6	rate of the TVT-Secur was equivalent to the	6	Q. Would it have been reasonable for
7	efficacy of the TVT and TVT-O?	7	physicians who were provided this marketing piece
8	MR. SNELL: Objection.	8	to believe based on the information Ethicon was
9	BY THE WITNESS:	9	providing to them that the TVT-Secur was as
10	A. Yes.	10	efficacious as the TVT Retropubic device?
11	BY MR. THORNBURGH:	11	MR. SNELL: Objection.
12	Q. Was that a misrepresentation? Strike	12	BY THE WITNESS:
13	that.	13	A. It would not be an unreasonable
14	Do you have an opinion whether or not	14	assumption.
15	that was a true claim?	15	BY MR. THORNBURGH:
16	MR. SNELL: Objection.	16	Q. Would it be reasonable for consumers to
17	BY THE WITNESS:	17	expect that the TVT-Secur would perform at least as
18	A. Yes, I have an opinion.	18	well as the TVT Retropubic or TVT-Obturator
19	BY MR. THORNBURGH:	19	devices?
20	Q. What's the opinion?	20	MR. SNELL: Objection.
21	MR. SNELL: Same.	21	BY THE WITNESS:
22	BY THE WITNESS:	22	A. Based on this brochure, one would
23	A. That was not a true claim.	23	could make that assumption.
24	BY MR. THORNBURGH:	24	BY MR. THORNBURGH:
_	Page 251		Page 253
1	Q. Do you have an opinion whether or not	1	Q. Any other information that you'd like to
2	that was a proven claim?	2	discuss concerning the information in this exhibit, Exhibit P1352?
3	A. Yes, I have an opinion.	3	
4	MR. SNELL: Same objection.	4	A. The next page, it states, "Gynecare's
5	BY MR. THORNBURGH:	5	commitment to evidence-based medicine, ongoing
6	Q. What's that opinion?	7	studies with the TVT-Secur, a post-market
7	A. That it was not a proven claim.	l _	evaluation of 50 patients and a prospective multi-center study with 300 patients."
8	Q. Do you have an opinion whether or not it	8	
9 10	was appropriate for Ethicon to represent to	10	Q. Based on your review of, in this case,
10	physicians that the TVT-Secur had equivalent	10	of Ethicon's internal documents, was Gynecare committed to evidence-based medicine?
11 12	efficacy or worked just as well as the TVT-Secur TVT strike that. Let me reask because I messed	12	A. They did not sponsor a prospective or
13		13	they did not perform their own prospective
14	up.  Do you have an opinion whether or not it	14	randomized multi-center trial of 300 patients.
15	was appropriate for Ethicon to represent to	15	MR. SNELL: Objection. Non-responsive. Move
16	physicians that the TVT-Secur was equivalent in	16	to strike.
17	efficacy as the TVT Retropubic or TVT-Obturator?	17	BY MR. THORNBURGH:
18	MR. SNELL: Same objection.	18	Q. Hold on a second. This is a marketing
19	BY THE WITNESS:	19	piece that Ethicon would use after the TVT-Secur
20	A. Yes, I have an opinion.	20	was on the market?
21	BY MR. THORNBURGH:	21	A. Correct.
22	Q. What is that opinion?	22	Q. After by the time Ethicon had brought
23	A. That that would be a misrepresentation.	23	the TVT-Secur to market and had begun to sell it,
	-		
24	Q. Did Ethicon tell physicians in this	24	had they already looked at the interim data for

1 2 3 4	this first study that they discuss here under the statement that Gynecare was committed to	1	BY THE WITNESS:
3			
	statement that Gynecare was committed to	2	A. Yes.
1	evidence-based medicine?	3	BY MR. THORNBURGH:
l 4	A. Yes.	4	Q. Do you have an opinion whether or not
5	Q. And did the interim data that Ethicon	5	the data from the interim First Human Use Study
6	reviewed from the First Human Use Study, did that	6	would have would have been beneficial to
7	demonstrate that the evidence supported the safety	7	implanting physicians when performing their
8	or efficacy of Ethicon's Secur product?	8	risk/benefit assessment?
9	MR. SNELL: Object.	9	MR. SNELL: Object.
10	BY THE WITNESS:	10	BY THE WITNESS:
11	A. That study did not.	11	A. Yes.
12	BY MR. THORNBURGH:	12	BY MR. THORNBURGH:
13	Q. Is this statement something that would	13	Q. Why is that?
14	have been reasonable for doctors to rely on?	14	MR. SNELL: Same.
15	MR. SNELL: Objection.	15	BY THE WITNESS:
16	BY THE WITNESS:	16	A. Doctors need all the information
17	A. It	17	available to them about the success and the
18	BY MR. THORNBURGH:	18	complications associated with a medical device in
19	Q. Strike that. Let me ask a better	19	order to make an accurate risk/benefit analysis to
20	question.	20	determine whether or not they would use a
21	Rather than tell doctors that you are as	21	particular device to treat a particular condition.
22	a company committed to evidence-based medicine,	22	BY MR. THORNBURGH:
23	would it have been appropriate instead for Ethicon	23	Q. Based on your review of Ethicon's
24	to disclose in this promotional piece the interim	24	internal company documents, did it ever edit this
	Page 255		Page 257
1	data from the First Human Use Study?	1	brochure that it provided to doctors?
2	MR. SNELL: Object.	2	MR. SNELL: Objection.
3	BY THE WITNESS:	3	BY THE WITNESS:
4	A. That would have been appropriate.	4	A. No, they did not.
5	BY MR. THORNBURGH:	5	BY MR. THORNBURGH:
6	Q. Did they do that?	6	Q. Did Ethicon ever edit this promotional
7	MR. SNELL: Same.	7	marketing piece that it provided to doctors to
8	BY THE WITNESS:	8	disclose the interim data from the First Human Use
9	A. No, they did not.	9	Study?
10	BY MR. THORNBURGH:	10	A. No, they did not.
11	Q. Could they have?	11	Q. Did Ethicon ever edit this brochure or
12	MR. SNELL: Same.	12	provide an updated brochure or create a new
13	A. Yes.	13	brochure that disclosed to implanting physicians
14	BY MR. THORNBURGH:	14	the final results from the 12 12-month First
15	Q. Should they have?	15	Human Use Data Study?
16	MR. SNELL: Same objection.	16	A. No, they did not.
17	BY THE WITNESS:	17	Q. Could they have?
18	A. Yes.	18	A. Yes.
19	BY MR. THORNBURGH:	19	Q. Should they have?
20	Q. What is the risk is there a risk of	20	A. Yes.
21	harm to patients if companies like Ethicon don't	21	MR. SNELL: Object.
	completely and accurately disclose the safety or	22	BY MR. THORNBURGH:
22			
22 23	efficacy information that they have?	23	Q. We are going to talk about the 12-month

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	Page 258		Page 260
1	of that study?	1	patients, and it the discussion shows that the
2	A. That the success rate was less than 70%	2	interim data is not good. It showed the higher
3	and the complication rate was 60%.	3	failure rate that was the primary endpoint. It
4	Q. Did that company did that 12-month	4	also showed a higher complication rate.
5	study pass or strike that.	5	Q. Okay. So, let me try to dissect this a
6	Did that 12-month study support the	6	little bit.
7	safety or efficacy of the TVT-Secur product?	7	Was it's dated August 26, 2006
8	A. No, it did not.	8	A. Correct.
9	Q. Did that study fail or pass, in other	9	Q is that correct?
10	words, did the study results demonstrate safety and	10	And how many months before the launch of
11	efficacy?	11	the TVT-Secur?
12	MR. SNELL: Object.	12	A. This is less than one month.
13	BY THE WITNESS:	13	Q. So, less than one month before Ethicon
14	A. No, it did not.	14	launched the TVT-Secur, is that correct?
15	BY MR. THORNBURGH:	15	A. Correct.
16	Q. Did the study fail to meet its primary	16	Q. And and you've already testified that
17	endpoints for safety?	17	the only relevant human data that was available to
18	A. Yes.	18	demonstrate safety or efficacy of the TVT-Secur
19	Q. Did the study fail to meet its primary	19	device was this First Human Use Study, is that
20	endpoints for efficacy?	20	correct?
21	A. Yes.	21	MR. SNELL: Objection and leading.
22	Q. Did Ethicon ever disclose that to any	22	BY THE WITNESS:
23	doctors in the community?	23	A. Correct.
24	A. No.	24	BY MR. THORNBURGH:
1		1	Q. Was there any other human study that
2	Q. What's the next exhibit you'd like to discuss, Doctor?	2	demonstrate or that was available to demonstrate
3	A. P1403.	3	safety or efficacy of the TVT-Secur device at this
4	MR. THORNBURGH: One moment.	4	time other than this First Human Use Study of 31
5	BY MR. THORNBURGH:	5	patients for five weeks?
6	Q. And what is Exhibit	6	MR. SNELL: Object.
7	THE VIDEOGRAPHER: Your microphone.	7	BY THE WITNESS:
8	BY MR. THORNBURGH:	8	A. No.
9	Q. Doctor, did you review and rely upon	9	BY MR. THORNBURGH:
10	P1403?	10	Q. And Allison London Brown in this e-mail
11	(Clarification requested by the	11	is writing to David Robinson who is the Medical
12	reporter.)	12	Affairs person, is that correct?
13	BY MR. THORNBURGH:	13	A. He is Medical Director, yes.
1 -2	2. Into Intole Delicit.		
14	O. Did you review and rely on	1 14	() And she writes in this e-mail in the
14 15	Q. Did you review and rely on Exhibit P1403?	14	Q. And she writes in this e-mail in the
15	Exhibit P1403?	15	very bottom of the first page, "Anna and David,
15 16	Exhibit P1403? A. Yes.	15 16	very bottom of the first page, "Anna and David, First, thanks for getting this so quickly - you've
15 16 17	Exhibit P1403? A. Yes. Q. And what is Exhibit P1403?	15 16 17	very bottom of the first page, "Anna and David, First, thanks for getting this so quickly - you've done a great job here. The data looks really
15 16 17 18	Exhibit P1403? A. Yes. Q. And what is Exhibit P1403? A. It's an e-mail string between David	15 16 17 18	very bottom of the first page, "Anna and David, First, thanks for getting this so quickly - you've done a great job here. The data looks really promising."
15 16 17 18 19	Exhibit P1403? A. Yes. Q. And what is Exhibit P1403? A. It's an e-mail string between David Robinson, Allison London Brown and other Ethicon	15 16 17 18 19	very bottom of the first page, "Anna and David, First, thanks for getting this so quickly - you've done a great job here. The data looks really promising."  Did I read that correctly?
15 16 17 18 19 20	Exhibit P1403? A. Yes. Q. And what is Exhibit P1403? A. It's an e-mail string between David Robinson, Allison London Brown and other Ethicon employees.	15 16 17 18 19 20	very bottom of the first page, "Anna and David, First, thanks for getting this so quickly - you've done a great job here. The data looks really promising."  Did I read that correctly?  A. Yes.
15 16 17 18 19 20 21	Exhibit P1403?  A. Yes. Q. And what is Exhibit P1403? A. It's an e-mail string between David Robinson, Allison London Brown and other Ethicon employees. Q. And how, if at all, does this exhibit	15 16 17 18 19 20 21	very bottom of the first page, "Anna and David, First, thanks for getting this so quickly - you've done a great job here. The data looks really promising."  Did I read that correctly?  A. Yes.  MR. SNELL: Objection; leading.
15 16 17 18 19 20 21 22	Exhibit P1403?  A. Yes.  Q. And what is Exhibit P1403?  A. It's an e-mail string between David Robinson, Allison London Brown and other Ethicon employees.  Q. And how, if at all, does this exhibit support your opinions?	15 16 17 18 19 20 21 22	very bottom of the first page, "Anna and David, First, thanks for getting this so quickly - you've done a great job here. The data looks really promising."  Did I read that correctly?  A. Yes.  MR. SNELL: Objection; leading. BY MR. THORNBURGH:
15 16 17 18 19 20 21	Exhibit P1403?  A. Yes. Q. And what is Exhibit P1403? A. It's an e-mail string between David Robinson, Allison London Brown and other Ethicon employees. Q. And how, if at all, does this exhibit	15 16 17 18 19 20 21	very bottom of the first page, "Anna and David, First, thanks for getting this so quickly - you've done a great job here. The data looks really promising."  Did I read that correctly?  A. Yes.  MR. SNELL: Objection; leading.

66 (Pages 258 to 261)

3 Q.	She was the worldwide launch coordinator	1	
3 Q.		1	A. Correct.
	TVT-Secur.	2	BY MR. THORNBURGH:
_	Okay. And was she a medical doctor?	3	Q. And do you understand what a what
	No.	4	does a positive cough test mean? What is that?
5 O.	And she is is she discussing here the	5	Explain to the ladies and gentlemen of the jury
	of the interim data?	6	what that test is and what the significance of that
	Yes.	7	test is, if any.
-	And she writes here that "How best do	8	A. A cough stress test is performed with a
_	ink we need to show the data?"	9	patient, most reliably in a standing position with
10	It's the first she is directing this	10	at least 200, 250 cc's of fluid in their bladder.
	on to Dave Thomas Dave Robinson at the	11	When they cough, if leakage is noted, that means
-	n of this page.	12	that there is a positive cough stress test. That
13	"Dave - How best do you think we need to	13	is a sign of stress urinary incontinence.
	he data? Right now it seems like it's a bit	14	Q. And eight out of 31 had positive cough
	e - text and numbers on the page, but is that	15	tests?
•	s needed at these meetings?"	16	A. Correct.
17 what is	And then another question, "Do you think	17	Q. And what does that mean, that eight out
		18	
	a jazz it up a bit?"  Did I road that correctly?	19	of 31 had positive cough tests?  A. That 26% of women leaked when they were
	Did I read that correctly?		
	S. SNELL: Objection; leading.	20	asked to cough.
	HE WITNESS:	21	Q. If there were four women in the room who
1	Yes.	22	underwent this procedure, how many of those women
	R. THORNBURGH:	23	would have leaked?
24 Q.	First of all, is it ever okay or	24	MR. SNELL: Objection.
	Page 263		Page 265
1 approp	riate for a medical device company to jazz up	1	BY THE WITNESS:
	or efficacy information?	2	A. One of them.
_	. SNELL: Object.	3	BY MR. THORNBURGH:
	IE WITNESS:	4	Q. If there were 100 patients at 100 at
5 A.	No.	5	31 days of the five-week period and they coughed,
6 BY MI	R. THORNBURGH:	6	how many of them would have leaked?
7 O.	Why not?	7	A. 26.
	Because a company should represent the	8	Q. Is that a high number in your opinion,
	e safety and efficacy data.	9	Doctor?
	Okay. And David Robinson responds back	10	A. Yes.
-	son. You've already testified about this,	11	Q. At five weeks?
	ant to talk about it a little bit in greater	12	A. Yes.
	"I am not sure I agree the data looks	13	Q. Is a 26% failure rate at five weeks good
14 good."		14	or bad for patients?
_	Is that correct?	15	MR. SNELL: Objection.
	Correct.	16	BY THE WITNESS:
	. SNELL: Leading. Object.	17	A. That is not a positive result.
	R. THORNBURGH:	18	BY MR. THORNBURGH:
	"You are talking about a 10% failure	19	Q. Do you have an opinion whether or not a
-	the primary endpoint and eight out of 31	20	26% failure rate was a good or bad result in this
	e cough tests in our secondary endpoints."	21	study?
-	Did I read that correctly?	22	•
	. SNELL: Object; leading.	23	MR. SNELL: Objection. BY THE WITNESS:
	E WITNESS:	24	A. It was a bad result.
	IL WITHESS.	44	A. It was a bad result.

67 (Pages 262 to 265)

	Page 266		Page 268
1	BY MR. THORNBURGH:	1	BY MR. THORNBURGH:
2	Q. Do you agree with David Robinson that	2	Q. Does that statement have any
3	the results of the TVT-Secur five-week study in 31	3	significance to your opinions?
4	patients did not look good?	4	MR. SNELL: Objection.
5	MR. SNELL: Object; misstates.	5	BY THE WITNESS:
6	BY THE WITNESS:	6	A. Yes.
7	A. I agree with that statement.	7	BY MR. THORNBURGH:
8	BY MR. THORNBURGH:	8	Q. And what is that?
9	Q. Are those your words?	9	MR. SNELL: Same.
10	A. Those are Dr. Robinson's words.	10	BY THE WITNESS:
11	Q. Do you agree with Dr. Robinson?	11	A. That well, first the learning curve,
12	A. That the data does not look good, yes.	12	again, is the amount of time it takes a physician
13	Q. Now	13	to feel to be able to reliably perform a
14	MR. SNELL: Move to strike.	14	procedure to get the best possible results.
15	BY MR. THORNBURGH:	15	It was initially anticipated that the
16	Q. Dr. Robinson goes on and says,	16	learning curve would be much shorter than it
17	"I believe these numbers will improve as the other	17	actually turned out to be. The learning curve was
18	half of the patients get done. But these first 31	18	initially anticipated to be maybe five to ten
19	include everyone's learning curve."	19	cases, but was found by the opinions and internal
20	Did I read that correctly?	20	documents from Key Opinion Leaders to be over 50
21	A. Yes.	21	and closer to 100.
22	Q. What's a learning curve?	22	Q. Do you have an opinion whether or not a
23	A. It is the amount of time that it takes	23	learning curve of 50 to 100 is a reasonable
24	for someone to become proficient at a surgical	24	learning curve for a medical device product?
	for someone to become proficient at a surgical		learning curve for a medical device product.
	Page 267		Page 269
			1496 209
1	technique.	1	MR. SNELL: Object.
1 2	technique. Q. What is Dr. Robinson	1 2	
	1		MR. SNELL: Object.
2	Q. What is Dr. Robinson	2	MR. SNELL: Object. BY THE WITNESS:
2	Q. What is Dr. Robinson THE WITNESS: Can we take a break?	2	MR. SNELL: Object. BY THE WITNESS: A. It is an unreasonable learning curve.
2 3 4	Q. What is Dr. Robinson THE WITNESS: Can we take a break? MR. THORNBURGH: Yes.	2 3 4	MR. SNELL: Object. BY THE WITNESS: A. It is an unreasonable learning curve. In fact, there were doctors that stated that even
2 3 4 5	Q. What is Dr. Robinson THE WITNESS: Can we take a break? MR. THORNBURGH: Yes. THE VIDEOGRAPHER: The time is 3:30 p.m. and	2 3 4 5	MR. SNELL: Object. BY THE WITNESS: A. It is an unreasonable learning curve. In fact, there were doctors that stated that even with training and re-training, they could still not
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2 3 4 5 6 7	Q. What is Dr. Robinson THE WITNESS: Can we take a break? MR. THORNBURGH: Yes. THE VIDEOGRAPHER: The time is 3:30 p.m. and we're going off the video record. (WHEREUPON, a recess was had	2 3 4 5 6 7	MR. SNELL: Object. BY THE WITNESS:  A. It is an unreasonable learning curve. In fact, there were doctors that stated that even with training and re-training, they could still not get the same the results that they were striving for.
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68 (Pages 266 to 269)

<u> </u>			
İ	Page 270		Page 272
1	A. That's what Dr. Robinson is saying.	1	sitting in New Jersey making a decision about what
2	BY MR. THORNBURGH:	2	to do with this information, instead of
3	Q. Since I got an objection.	3	Dr. Robinson, it was you, Dr. Rosenzweig, faced
4	What is your understanding of what	4	with the same facts and the same data, what would
5	Dr. Robinson is suggesting with respect to the	5	Dr. Rosenzweig have decided to do? What choice
6	learning curve and the additional patients that	6	would you have made?
7	would be added to the study?	7	MR. SNELL: Object.
8	A. He is stating that he believes that the	8	BY THE WITNESS:
9	numbers will get better in the second half of the	9	A. I would not have launched the TVT-Secur
10	study. The study was to look at 60 women.	10	on September 20, 2006.
11	Ultimately 72 women were in the final analysis of	11	BY MR. THORNBURGH:
12	the First Human Use data, and he was anticipating	12	Q. And did you read the trial testimony of
13	that the success rates would go up and the	13	Dr. Sepulveda?
14	complication rate would go down.	14	A. Yes.
15	Q. Now, was Dr. Robinson correct that after	15	Q. And what did Dr. Sepulveda testify to
16	the learning curve had been achieved, that the	16	with respect to the same question I asked him, if
17	results would get better?	17	it were Dr. Sepulveda with this information in
18	A. No, he was not.	18	August of 2006, what would he have done, what did
19	Q. And how do you know that? What's the	19	he testify to?
20	basis for your opinion?	20	A. If
21	A. The final data from the First Human Use	21	MR. SNELL: Object.
22	Study.	22	BY THE WITNESS:
23	Q. Now, do medical device companies have	23	A. If I recall correctly, he said he would
24	choices?	24	delay the launch too.
	Page 271		Page 273
1	MR. SNELL: Objection.	1	BY MR. THORNBURGH:
2	BY THE WITNESS:	2	Q. So, do you agree with Dr. Sepulveda on
3	A. Yes.	3	that issue?
4	BY MR. THORNBURGH:	4	A. Yes.
5	Q. Do the employees that work for medical	5	Q. Do you agree and what decision did
6	device companies have choices?	6	Dr. David Robinson choose?
7	MR. SNELL: Objection.	7	A. To continue with the launch of the
8	BY THE WITNESS:	8	TVT-Secur on September 20, 2006.
9	A. Yes.	9	Q. Was that an appropriate choice?
10	BY MR. THORNBURGH:	10	A. No.
11	Q. Did David Robinson have a choice in	11	Q. Did do you have an opinion whether or
12	August on August 26, 2006 with respect to the	12	not Dr. Sepulveda's choice to continue with the
13	data he had available to him prior to launch?	13	launch of the product in light of the data he had
14	MR. SNELL: Objection.	14	available to him before launch
15	BY THE WITNESS:	15	A. Dr. Robinson.
16	A. Yes.	16	Q. Sorry. Strike that.
17	BY MR. THORNBURGH:	17	Do you have an opinion whether or not
18	Q. What choices did he have?	18	Dr. Robinson's choice to continue to launch
19	A. He could say that this data does not	19	continue with the launch of the TVT-Secur product
20	look good and we should delay the launch or even	20	in light of this data was appropriate?
21	not continue the product line because the data	21	MR. SNELL: Object.
Z J	_	22	BY THE WITNESS:
	was showed a high failure rate and a high	22.	
22	was showed a high failure rate and a high complication rate.		
	was showed a high failure rate and a high complication rate.  Q. Now, if instead of David Robinson	23 24	A. Yes, I have an opinion. BY MR. THORNBURGH:

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	Page 274		Page 276
1	Q. What is that opinion?	1	A. The data did not get better. In fact,
2	MR. SNELL: Same.	2	it got worse.
3	BY THE WITNESS:	3	Q. And what
4	A. It was not appropriate.	4	A. The failure data.
5	BY MR. THORNBURGH:	5	Q. And what was the failure rate?
6	Q. And why wasn't it appropriate?	6	A. Above 30%, if I recall.
7	A. Because the device was shown to have	7	Q. And is it fair to say approximately 30%
8	characteristics that made it unreasonably unsafe	8	of the patients who were treated with the TVT-Secur
9	and unreasonably ineffective.	9	in the First Human Use Study failed the procedure
10	Q. And did this decision do you have an	10	to treat their stress urinary incontinence?
11	opinion whether or not the decision to launch this	11	A. Correct.
12	product impacted the safety of patients?	12	MR. SNELL: Object and leading.
13	A. Yes.	13	BY MR. THORNBURGH:
14	Q. And what is that opinion?	14	Q. And what was what did Dr. Robinson
15	A. That it negatively impacted the safety	15	testify to with respect to the complication rate
16	of women.	16	seen by him in the final interim data of the First
17	Q. In what way?	17	Human Use Study?
18	A. It had an unreasonably high failure rate	18	A. That the complication data did not go
19	and an unreasonably high complication rate.	19	down either.
20	Q. What's the next document you want to	20	Q. And do you recall what the complication
21	discuss with the jury?	21	rate was, approximately?
22	A. It is an e-mail from September 25, 2006.	22	A. Approximately 60%.
23	Q. Well, hold on one second. Before we do	23	Q. Did the First Human Use final interim
24	that really quick.	24	analysis of 31 patients at five weeks demonstrate
21	that really quiek.	21	analysis of 51 patients at five weeks demonstrate
	Page 275		Page 277
1	Did you read and rely on the testimony	1	safety or efficacy of the TVT-Secur product?
2	of Dr. Robinson?	2	MR. SNELL: Object.
3	A. Yes.	3	BY THE WITNESS:
4	Q. And did Dr. Robinson what did	4	A. No, it did not.
5	Dr. Robinson testify with respect to the final	5	BY MR. THORNBURGH:
6	results from the that short-term, five-week, 31	6	Q. What's the next document you have with
7	patient interim data that he had available to him?	7	you?
8	MR. SNELL: Objection.	8	(Reporter note: Exhibit P1452.)
9	BY MR. THORNBURGH:	9	BY THE WITNESS:
10	Q. Prior to launch.	10	A. It is an e-mail from between David
11	MR. SNELL: Sorry. Objection.	11	Robinson and Harel Gadot. It is regarding an
12	BY THE WITNESS:	12	e-mail from an Israeli physician Dr. Flam regarding
13	A. The final 12-month analysis after the	13	defects associated with the TVT-Secur.
14	study was completed?	14	Q. And what is the date of this e-mail?
15	BY MR. THORNBURGH:	15	A. September 25, 2006.
16	Q. Yeah, let me ask a better question.	16	Q. In terms of the date that the TVT-Secur
17	Did you read and rely on Dr. Robinson's	17	was launched, how close in time was this e-mail
18	testimony concerning the final results of the	18	sent?
19	interim First Human Use data?	19	A. Five days after launch.
20	A. Yes.	20	Q. Okay. And did you review and rely on
21	Q. And what did Dr. Robinson testify to	21	this exhibit in forming your opinions in this case?
22	with respect to the failure rate, if any, of the	22	A. Yes.
23	TVT-Secur device as found in the final interim	23	Q. And what about this exhibit did you rely
	1 . 1 Seeds de sièc de found in the final intelli	1 -0	2. The what about this exhibit did you left
24	data?	24	on in forming your opinions in this case?

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	Page 278		Page 280
1	A. I relied on the fact that a physician	1	off to Dr. Robinson and said, "Please do not
2	who was using this device at the time who was a	2	distribute."
3	skilled pelvic surgeon communicated with Ethicon	3	BY MR. THORNBURGH:
4	that the device was defective.	4	Q. And what is the significance of that
5	Q. Is it fair to say that strike that.	5	response from Dr. Gadot saying, "FYI - please do
6	If we can, go ahead and just pull up	6	not distribute"?
7	this exhibit on the screen and go to the full	7	A. Well, if this information about the
8	e-mail from Dr. Suchard or Mr. Suchard. Very	8	defects associated with the TVT-Secur device are
9	bottom part.	9	not distributed to to others, then it would be
10	And what is occurring in this	10	difficult or impossible for doctors to know about
11	conversation with Dr. Suchard to Dr. Flam Folke?	11	the defects, the characteristics of the device that
12	MR. SNELL: Objection.	12	make it defective and that make it unreasonably
13	BY MR. THORNBURGH:	13	unsafe or unreasonably ineffective and therefore
14	Q. What part of this what part of this	14	cannot pass that information on to their patients
15	e-mail conversation is relevant to your opinions?	15	to have an adequate, informed discussion about the
16	A. Well, first, Dr. Flam is being invited	16	risks associated with the TVT-Secur device.
17	to some professional education events for TVT-Secur	17	Q. Do you have an opinion about whether or
18	and Prolift from the Gynecare team leader from	18	not Ethicon appropriately responded to the concerns
19	Johnson & Johnson medical in Israel.	19	being raised by Dr. Flam Folke?
20	Q. Did I'm sorry. Go ahead. Go ahead.	20	MR. SNELL: Object.
21	A. And then Dr. Flam responds back that he	21	BY THE WITNESS:
22	has concerns regarding the TVT-Secur. He feels	22	A. I do have an opinion.
23	that the product needs to be adjusted before he's	23	BY MR. THORNBURGH:
24	willing to demonstrate it. He describes that there	24	Q. What's that opinion?
	Page 279		Page 281
1	are defects that have to be attended to.	1	A. They did not.
2	Q. And did do you agree	2	Q. And how so?
3	MR. SNELL: I'm sorry. Move to strike.	3	A. They did not distribute this information
4	BY MR. THORNBURGH:	4	from a surgeon who noted that there were defects
5	Q. Do you agree based on your review of	5	associated with the TVT-Secur.
6	the strike that.	6	Q. Do you have an opinion whether or not
7	Do you agree with Dr. Flam Folke or	7	Ethicon had enough information at this point in
8	Folke?	8	time to take proper action and, as Dr. Folke
9	A. Yes.	9	writes, address or attend to some of the defects?
10	Q. And what part of Dr. Flam Folke's e-mail	10	MR. SNELL: Object.
11	do you agree with?	11	BY THE WITNESS:
12	MR. SNELL: Object.	12	A. Yes, they did have enough information.
13	BY THE WITNESS:	13	BY MR. THORNBURGH:
14	A. That there are defects associated with	14	Q. What information did they have?
	the TVT-Secur.	15	A. The data from the First Human Use Study.
15 16	BY MD THODNRIDCH	1 6	
16	BY MR. THORNBURGH:	16	Q. And did Ethicon attempt in any way to
16 17	Q. And how did Ethicon or Ethicon's	17	correct or address the physical characteristics of
16 17 18	Q. And how did Ethicon or Ethicon's employees respond to this comment by Dr. Folke that	17 18	correct or address the physical characteristics of the TVT-Secur device from the date that they
16 17 18 19	Q. And how did Ethicon or Ethicon's employees respond to this comment by Dr. Folke that the TVT-Secur had some defects that needed to be	17 18 19	correct or address the physical characteristics of the TVT-Secur device from the date that they launched it until they finally stopped selling the
16 17 18 19 20	Q. And how did Ethicon or Ethicon's employees respond to this comment by Dr. Folke that the TVT-Secur had some defects that needed to be attended to?	17 18 19 20	correct or address the physical characteristics of the TVT-Secur device from the date that they launched it until they finally stopped selling the product in 2012?
16 17 18 19 20 21	Q. And how did Ethicon or Ethicon's employees respond to this comment by Dr. Folke that the TVT-Secur had some defects that needed to be attended to?  A. When it went up to	17 18 19 20 21	correct or address the physical characteristics of the TVT-Secur device from the date that they launched it until they finally stopped selling the product in 2012?  MR. SNELL: Object.
16 17 18 19 20 21 22	Q. And how did Ethicon or Ethicon's employees respond to this comment by Dr. Folke that the TVT-Secur had some defects that needed to be attended to?  A. When it went up to MR. SNELL: Object.	17 18 19 20 21 22	correct or address the physical characteristics of the TVT-Secur device from the date that they launched it until they finally stopped selling the product in 2012?  MR. SNELL: Object. BY THE WITNESS:
16 17 18 19 20 21	Q. And how did Ethicon or Ethicon's employees respond to this comment by Dr. Folke that the TVT-Secur had some defects that needed to be attended to?  A. When it went up to	17 18 19 20 21	correct or address the physical characteristics of the TVT-Secur device from the date that they launched it until they finally stopped selling the product in 2012?  MR. SNELL: Object.

	Page 282		Page 284
1	Q. And do you have an opinion about whether	1	BY THE WITNESS:
2	or not that was appropriate?	2	A to treat their stress urinary
3	A. I do have an opinion.	3	incontinence and the complications associated with
4	Q. And what's that opinion?	4	the device, including erosion, pain, pain with
5	MR. SNELL: Object.	5	intercourse, obstructed voiding, irritative voiding
6	BY THE WITNESS:	6	symptoms that I've described earlier in prior
7	A. It is inappropriate.	7	testimony.
8	BY MR. THORNBURGH:	8	BY MR. THORNBURGH:
9	Q. And what should the company do?	9	Q. Could Ethicon have taken action,
10	MR. SNELL: Same objection.	10	different action?
11	BY THE WITNESS:	11	MR. SNELL: Object.
12	A. Stop selling the device.	12	BY THE WITNESS:
13	BY MR. THORNBURGH:	13	A. Yes.
14	Q. How many years did it take after	14	BY MR. THORNBURGH:
15	Dr. Folke's or Folke's e-mail with the comment that	15	Q. Should Ethicon have responded and
16	there were some defects that needed to be attended	16	attended to the defects?
17	to before Ethicon stopped selling the device?	17	A. Yes.
18	A. Six years.	18	MR. SNELL: Object.
19	Q. And all this time, the six-year period,	19	BY MR. THORNBURGH:
20	did doctors continue to implant the TVT-Secur	20	Q. Is there anything else significant from
21	product into patients?	21	that exhibit?
22	A. Yes.	22	A. No.
23	Q. Did Ethicon's failure to properly	23	Q. What's the next exhibit that you have
24	respond to the data from their First Human Use	24	and wish to discuss with the jury?
	respond to the data from their rist ridinal Cise		and wish to discuss with the july.
	Page 283		Page 285
1	Study and to the concerns of Dr. Folke put patients	1	A. It is an e-mail string between Ethicon
2	at risk?	2	employees Carolyn Brennan and Mark Yale discussing
3	MR. SNELL: Object and leading.	3	the learning curve and complications that are being
4	BY THE WITNESS:	4	reported to Ethicon.
5	A. Yes.	5	Q. Okay. And can you identify the exhibit
6	BY MR. THORNBURGH:	6	number for the ladies and gentlemen of the jury?
7	Q. Do you have an opinion whether or not	7	A. P0274.
8	Ethicon's failure to respond by attending to the	8	Q. Okay. And what's the date of this
9	defects put patients at risk of harm?	9	e-mail string?
10	MR. SNELL: Object.	10	A. November 3, 2006.
11	BY THE WITNESS:	11	Q. And did you review and rely on this
12	A. Yes, I have an opinion.	12	exhibit?
13	BY MR. THORNBURGH:	13	A. Yes.
14	Q. What's that opinion?	14	A. Yes. Q. And what, if anything, is significant to
15	MR. SNELL: Same.		
16	WK. SNELL: Same. BY THE WITNESS:	15	your opinions in Exhibit 274?
16 17		16	A. Based on the complications and
	A. That my opinion is that that not	17	difficulties that surgeons are having, one of the
18	attending to the defects associated with the device	18	Ethicon employees who's Project Manager, Worldwide
1 0	put patients at harm.	19	Customer Quality, Cary Brennan, is raising concerns
19	• •		
20	BY MR. THORNBURGH:	20	about whether it is the surgeon's learning curve,
20 21	BY MR. THORNBURGH:  Q. What types of harm are patients put at	21	it is the technique of insertion or is it an inmate
20 21 22	BY MR. THORNBURGH:  Q. What types of harm are patients put at risk of suffering from?	21 22	it is the technique of insertion or is it an inmate problem with the device, a defect with the device
20 21	BY MR. THORNBURGH:  Q. What types of harm are patients put at	21	it is the technique of insertion or is it an inmate

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I	Page 286		Page 288
1	Q. And do you what was the subject that	1	then the device not continued or removed from the
2	Ethicon employees were discussing in this e-mail?	2	market.
3	A. Difficulties with insertion of the	3	BY MR. THORNBURGH:
4	device.	4	Q. What's is there anything else
5	Q. Okay. And the I think the question	5	significant about that last exhibit?
6	that you discussed was, if you look at Exhibit 274,	6	A. No.
7	it says, "Our concern is whether this is the	7	Q. What's the next exhibit that you'd like
8	surgeon's learning curve, technique issue or a	8	to discuss?
9	problem with the device."	9	A. Again, it is Exhibit P1096. It is an
10	Did I read that correctly?	10	e-mail string between key Ethicon employees, Dr
11	MR. SNELL: Objection; leading too.	11	excuse me Harel Gadot of marketing and Ralf
12	BY THE WITNESS:	12	Felix Gotter, who is the country director of
13	A. Correct.	13	Ethicon in Germany.
14	BY MR. THORNBURGH:	14	Q. And what what was the subject of the
15	Q. And how many months after the TVT-Secur	15	discussion being held between these Ethicon
16	product had already been launched into the	16	employees on November 30 of 2006?
17	worldwide market to be implanted permanently in	17	A. Yes. More procedures, more problems.
18	women did people or employees at Ethicon discuss	18	Q. And how is this document relevant, if at
19	these concerns?	19	all, to your opinions in this case?
20	A. Approximately six weeks after launch.	20	A. This is documenting the defects
21	Q. Do you have an opinion whether or not	21	associated with the device, which are leading to
22	these concerns should have been discussed and	22	harm in women, which are now being reported to
23	determined and attended to before the product had	23	Ethicon.
24	ever been launched?	24	The more procedures that are being done,
	Page 287		Page 289
1	A. Yes, I have an opinion.	1	the more complications that are occurring,
2	MR. SNELL: Objection; leading.	2	demonstrating the characteristics of the device
3	BY MR. THORNBURGH:	3	that are unreasonably unsafe.
4	Q. What's that opinion?		•
		4	Q. And was it appropriate strike that.
5	MR. SNELL: Same.	5	<ul><li>Q. And was it appropriate strike that.</li><li>Is there anything else relevant to this</li></ul>
6	MR. SNELL: Same. BY THE WITNESS:	5 6	Q. And was it appropriate strike that.  Is there anything else relevant to this exhibit or significant to your opinions with
	MR. SNELL: Same. BY THE WITNESS: A. That these issues should have been	5	Q. And was it appropriate strike that.  Is there anything else relevant to this exhibit or significant to your opinions with respect to this exhibit?
6 7 8	MR. SNELL: Same. BY THE WITNESS: A. That these issues should have been attended to prior to launch.	5 6 7 8	Q. And was it appropriate strike that.  Is there anything else relevant to this exhibit or significant to your opinions with respect to this exhibit?  A. No.
6 7 8 9	MR. SNELL: Same. BY THE WITNESS: A. That these issues should have been attended to prior to launch. BY MR. THORNBURGH:	5 6 7 8 9	<ul> <li>Q. And was it appropriate strike that.</li> <li>Is there anything else relevant to this exhibit or significant to your opinions with respect to this exhibit?</li> <li>A. No.</li> <li>Q. What's the next document in your binder?</li> </ul>
6 7 8 9	MR. SNELL: Same. BY THE WITNESS: A. That these issues should have been attended to prior to launch. BY MR. THORNBURGH: Q. And what could Ethicon have done	5 6 7 8 9	<ul> <li>Q. And was it appropriate strike that.</li> <li>Is there anything else relevant to this exhibit or significant to your opinions with respect to this exhibit?</li> <li>A. No.</li> <li>Q. What's the next document in your binder?</li> <li>A. It is an e-mail string between David</li> </ul>
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MR. SNELL: Same. BY THE WITNESS:  A. That these issues should have been attended to prior to launch. BY MR. THORNBURGH:  Q. And what could Ethicon have done differently to attend to these issues to determine whether or not what is being reported here were a result of the learning curve, technique issue or problem with the device?  MR. SNELL: Object. BY THE WITNESS:  A. Studying the device in a prospective randomized controlled fashion or in other human use studies would have demonstrated the characteristics of the device that make it either difficult to insert or unreasonably unsafe for patients or	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. And was it appropriate strike that.  Is there anything else relevant to this exhibit or significant to your opinions with respect to this exhibit?  A. No.  Q. What's the next document in your binder?  A. It is an e-mail string between David Robinson, Medical Director, and other key Ethicon employees regarding concerns about the effectiveness of the device as seen by doctors who are teaching the procedure to other doctors, which are called preceptors, and also from the interim analysis of the First Human Use Study, demonstrating the characteristics of the device that make it unreasonably ineffective and leading to the harm of either not treating the stress urinary incontinence or recurrence of stress urinary incontinence.
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MR. SNELL: Same. BY THE WITNESS:  A. That these issues should have been attended to prior to launch. BY MR. THORNBURGH:  Q. And what could Ethicon have done differently to attend to these issues to determine whether or not what is being reported here were a result of the learning curve, technique issue or problem with the device?  MR. SNELL: Object. BY THE WITNESS:  A. Studying the device in a prospective randomized controlled fashion or in other human use studies would have demonstrated the characteristics of the device that make it either difficult to insert or unreasonably unsafe for patients or unreasonably ineffective for patients.	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. And was it appropriate strike that.  Is there anything else relevant to this exhibit or significant to your opinions with respect to this exhibit?  A. No.  Q. What's the next document in your binder?  A. It is an e-mail string between David Robinson, Medical Director, and other key Ethicon employees regarding concerns about the effectiveness of the device as seen by doctors who are teaching the procedure to other doctors, which are called preceptors, and also from the interim analysis of the First Human Use Study, demonstrating the characteristics of the device that make it unreasonably ineffective and leading to the harm of either not treating the stress urinary incontinence or recurrence of stress urinary incontinence.  Q. How many months after Ethicon had
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MR. SNELL: Same. BY THE WITNESS:  A. That these issues should have been attended to prior to launch. BY MR. THORNBURGH:  Q. And what could Ethicon have done differently to attend to these issues to determine whether or not what is being reported here were a result of the learning curve, technique issue or problem with the device?  MR. SNELL: Object. BY THE WITNESS:  A. Studying the device in a prospective randomized controlled fashion or in other human use studies would have demonstrated the characteristics of the device that make it either difficult to insert or unreasonably unsafe for patients or	5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. And was it appropriate strike that.  Is there anything else relevant to this exhibit or significant to your opinions with respect to this exhibit?  A. No.  Q. What's the next document in your binder?  A. It is an e-mail string between David Robinson, Medical Director, and other key Ethicon employees regarding concerns about the effectiveness of the device as seen by doctors who are teaching the procedure to other doctors, which are called preceptors, and also from the interim analysis of the First Human Use Study, demonstrating the characteristics of the device that make it unreasonably ineffective and leading to the harm of either not treating the stress urinary incontinence or recurrence of stress urinary incontinence.

73 (Pages 286 to 289)

	Page 290		Page 292
1	MR. SNELL: I'm sorry. I have to actually	1	BY MR. THORNBURGH:
2	object to as non-responsive and well beyond the	2	Q. Who is who is in the first who
3	question for the last answer.	3	is being addressed in this document?
4	BY MR. THORNBURGH:	4	A. Dharini Amin who is an Ethicon employee
5	Q. Let me ask you this question, Doctor.	5	of Johnson & Johnson.
6	What is the significance, if any, of this	6	Q. Okay. And David Robinson writes,
7	Exhibit P127 to your opinions?	7	"Dharini, on another note, I think Marketing (and
8	A. This e-mail string demonstrates that	8	you in particular) need to think about some issues
9	Ethicon had information regarding the poor efficacy	9	that are going to come forth with Secur."
10	in treating stress urinary incontinence or	10	Did I read that correctly?
11	·	11	•
	effectiveness in treating stress urinary		MR. SNELL: Object; leading. BY THE WITNESS:
12	incontinence of the TVT-Secur device within two	12	
13	months of launch.	13	A. Yes.
14	Q. Okay. And if we look at what	14	BY MR. THORNBURGH:
15	paragraph or part of Exhibit P127 supports your	15	Q. What, if any, significance does that
16	opinions?	16	sentence have with respect to your opinions?
17	A. The e-mail states, "It is apparent that	17	A. That sentence demonstrates that Ethicon
18	there is some level of concern re efficacy seen by	18	had knowledge as early as November 14, 2006 about
19	the preceptors," again, which are doctors that are	19	concerns with the TVT-Secur regarding its
20	training other doctors to do the technique, "as	20	effectiveness and characteristics of the device
21	well as within the interim analysis of the First	21	that made it unreasonably unsafe.
22	Human Use Trials."	22	MR. SNELL: Object. Move to strike. State of
23	Q. Okay. And where were these physicians	23	mind.
24	located who were raising concerns about the	24	BY MR. THORNBURGH:
			Page 293
1	TVT-Secur device and its efficacy?	1	Q. And he Dr. Robinson goes on and says
2	·		
/.	A Both U.S. precentors and European		
	A. Both U.S. preceptors and European, Middle East and Africa preceptors	2	or writes, "After listening to the U.S. preceptors
3	Middle East and Africa preceptors.	2 3	or writes, "After listening to the U.S. preceptors and also going to the EMEA," which we've already
3 4	Middle East and Africa preceptors.  Q. Okay. If Ethicon were to represent	2 3 4	or writes, "After listening to the U.S. preceptors and also going to the EMEA," which we've already established was the European Europe, Middle East
3 4 5	Middle East and Africa preceptors.  Q. Okay. If Ethicon were to represent that assume with me that at trial Ethicon, their	2 3 4 5	or writes, "After listening to the U.S. preceptors and also going to the EMEA," which we've already established was the European Europe, Middle East and Africa, "preceptor/early use meeting this
3 4 5 6	Middle East and Africa preceptors.  Q. Okay. If Ethicon were to represent that assume with me that at trial Ethicon, their experts or through argument, represents to the	2 3 4 5 6	or writes, "After listening to the U.S. preceptors and also going to the EMEA," which we've already established was the European Europe, Middle East and Africa, "preceptor/early use meeting this weekend in Paris, it is apparent that there is some
3 4 5 6 7	Middle East and Africa preceptors.  Q. Okay. If Ethicon were to represent that assume with me that at trial Ethicon, their experts or through argument, represents to the ladies and gentlemen of the jury that the problems	2 3 4 5 6 7	or writes, "After listening to the U.S. preceptors and also going to the EMEA," which we've already established was the European Europe, Middle East and Africa, "preceptor/early use meeting this weekend in Paris, it is apparent that there is some level of concern regarding efficacy seen by
3 4 5 6 7 8	Middle East and Africa preceptors.  Q. Okay. If Ethicon were to represent that assume with me that at trial Ethicon, their experts or through argument, represents to the ladies and gentlemen of the jury that the problems with the TVT-Secur device with respect to its	2 3 4 5 6 7 8	or writes, "After listening to the U.S. preceptors and also going to the EMEA," which we've already established was the European Europe, Middle East and Africa, "preceptor/early use meeting this weekend in Paris, it is apparent that there is some level of concern regarding efficacy seen by preceptors as well as within the interim analysis
3 4 5 6 7 8	Middle East and Africa preceptors.  Q. Okay. If Ethicon were to represent that assume with me that at trial Ethicon, their experts or through argument, represents to the ladies and gentlemen of the jury that the problems with the TVT-Secur device with respect to its efficacy were isolated to Australia or Germany,	2 3 4 5 6 7 8	or writes, "After listening to the U.S. preceptors and also going to the EMEA," which we've already established was the European Europe, Middle East and Africa, "preceptor/early use meeting this weekend in Paris, it is apparent that there is some level of concern regarding efficacy seen by preceptors as well as within the interim analysis of the First Human Use Trial."
3 4 5 6 7 8 9	Middle East and Africa preceptors.  Q. Okay. If Ethicon were to represent that assume with me that at trial Ethicon, their experts or through argument, represents to the ladies and gentlemen of the jury that the problems with the TVT-Secur device with respect to its efficacy were isolated to Australia or Germany, would that be an accurate statement?	2 3 4 5 6 7 8 9	or writes, "After listening to the U.S. preceptors and also going to the EMEA," which we've already established was the European Europe, Middle East and Africa, "preceptor/early use meeting this weekend in Paris, it is apparent that there is some level of concern regarding efficacy seen by preceptors as well as within the interim analysis of the First Human Use Trial."  Did I read that correctly?
3 4 5 6 7 8 9 10	Middle East and Africa preceptors.  Q. Okay. If Ethicon were to represent that assume with me that at trial Ethicon, their experts or through argument, represents to the ladies and gentlemen of the jury that the problems with the TVT-Secur device with respect to its efficacy were isolated to Australia or Germany, would that be an accurate statement?  MR. SNELL: Object.	2 3 4 5 6 7 8 9 10	or writes, "After listening to the U.S. preceptors and also going to the EMEA," which we've already established was the European Europe, Middle East and Africa, "preceptor/early use meeting this weekend in Paris, it is apparent that there is some level of concern regarding efficacy seen by preceptors as well as within the interim analysis of the First Human Use Trial."  Did I read that correctly?  MR. SNELL: Object and leading.
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	Page 294		Page 296
1	reporting that after the device was launched on to	1	BY THE WITNESS:
2	the market doctors throughout the world were having	2	A. Yes, by not launching the product or
3	the same problems that Ethicon, particularly	3	removing the product from the market.
4	Dr. David Robinson, was made aware of prior to	4	BY MR. THORNBURGH:
5	launching the product when he looked at the First	5	Q. I mean, we're not just talking about
6	Human Use data?	6	doctors having problems, are we?
7	MR. SNELL: Objection and leading.	7	MR. SNELL: Objection; leading, argumentative.
8	BY THE WITNESS:	8	Sorry. Go ahead.
9	A. Yes.	9	BY THE WITNESS:
10	BY MR. THORNBURGH:	10	A. No.
11	Q. What, if anything, is significant about	11	BY MR. THORNBURGH:
12	Dr. Robinson's statements here concerning the	12	Q. What are we talking about here?
13	problems that are being reported by Ethicon's	13	A. The safety
14	preceptors around the world in relationship to what	14	MR. SNELL: Same.
15	was seen before the product was launched by	15	BY THE WITNESS:
16	Dr. Robinson in the First Human Use interim data?	16	A of patients.
17	MR. SNELL: Objection.	17	BY MR. THORNBURGH:
18	BY THE WITNESS:	18	Q. And, so, when Dr. Robinson is talking
19	A. Dr. Robinson is reporting that doctors	19	about these preceptors who were reporting their
20	who are trying to implant the device are	20	concerns, is he is it your understanding that
21	experiencing the same degree of inability of the	21	he's that these concerns are with respect to
22	product to treat the stress urinary incontinence as	22	actual people?
23	was known from the First Human Use Study prior to	23	MR. SNELL: Object.
24	launch of the product.	24	BY THE WITNESS:
1	Page 295 BY MR. THORNBURGH:	1	Page 297 A. Yes.
2	Q. And you testified earlier about choices,	2	BY MR. THORNBURGH:
3	about how Ethicon and David Robinson in particular	3	Q. And, so, when you testified earlier that
4	had a choice when he looked at the first interim	4	Ethicon and David Robinson in particular had a
5	use data. Do you recall that?	5	choice and that they could have chosen to delay the
6	A. Yes.	6	launch to fix the problems or not to launch the
7	MR. SNELL: Objection; leading.	7	product at all and that by making the choice to put
8	BY MR. THORNBURGH:	8	the product on the market despite the First Human
9	Q. And do you recall the testimony about	9	Use data and how that could impact patient safety,
10	why those choices that he had were important?	10	is that what we're actually seeing in the real
11	A. Yes.	11	world?
12	Q. And what was your statement?	12	MR. SNELL: Object and leading.
13	MR. SNELL: Objection.	13	BY THE WITNESS:
14	BY THE WITNESS:	14	A. Yes.
15	A. That it is important to look at the data	15	BY MR. THORNBURGH:
16	to determine whether or not to go ahead with the	16	Q. Doctor, I got a leading objection.
17	launch of the product and based on the data, the	17	How does this document, Exhibit P127,
18	product should not have been launched.	18	support the prior testimony from you that it was
	BY MR. THORNBURGH:	19	inappropriate for Ethicon to release or launch the
19	Q. And the problems that were being	20	TVT-Secur data in light of the First Human Use
19 20	Q. That the problems that were being		
	expressed by Ethicon's preceptors both in the	21	Trial?
20	expressed by Ethicon's preceptors both in the United States and in other parts of the world,	21 22	Trial?  MR. SNELL: Same objection. No leading.
20 21	expressed by Ethicon's preceptors both in the		

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	Page 298		Page 300
1	having problems with the device and it was putting	1	BY THE WITNESS:
2	patients at harm.	2	A. Yes.
3	THE VIDEOGRAPHER: Counsel, can I end?	3	BY MR. THORNBURGH:
4	MR. THORNBURGH: We have to take a break for a	4	Q. Would that type of information have been
5	tape change.	5	important to you?
6	THE VIDEOGRAPHER: The time is 4:21 p.m. This	6	A. Yes.
7	is the end of Tape 3 and we're going off the video	7	Q. In what way?
8	record.	8	A. It would have been important to know
9	(WHEREUPON, a recess was had	9	whether a device is safe and effective to be used
10	from 4:21 to 4:31 p.m.)	10	in humans in order to decide what is the most
11	THE VIDEOGRAPHER: The time is 4:31 p.m. This	11	appropriate therapy to use in an individual
12	is the beginning of Tape 4 and we are back on the	12	patient.
13	video record.	13	Q. Is that the type of information that
14	BY MR. THORNBURGH:	14	physicians use in the method that we discussed
15	Q. Dr. Rosenzweig, before we went off the	15	earlier of the risk/benefit assessment when
16	record we were discussing Exhibit P127, and we're	16	deciding which surgical or treatment options should
17	almost through with this exhibit, but I want to	17	be made available to their patients?
18	take you back in time just a little bit.	18	MR. SNELL: Object.
19	This is November of 2006 when this	19	BY THE WITNESS:
20	discussion is occurring and, again, you testified	20	A. Yes.
21	that was just a couple months after Ethicon had	21	BY MR. THORNBURGH:
22	launched the product?	22	Q. Is there anything else relevant that you
23	A. Correct.	23	want to speak with the jury about concerning
24	Q. Now, you also testified earlier that	24	Exhibit 127?
			Page 301
1		1	Page 301 A. No.
1 2	shortly after the launch of the TVT-Secur, either	1 2	A. No.
	shortly after the launch of the TVT-Secur, either at the end of 2006 or beginning of 2007, you were		
2	shortly after the launch of the TVT-Secur, either at the end of 2006 or beginning of 2007, you were introduced to the TVT-Secur through Ethicon's sales	2	A. No. Q. What's the next document that you want to discuss?
2	shortly after the launch of the TVT-Secur, either at the end of 2006 or beginning of 2007, you were	2 3	<ul><li>A. No.</li><li>Q. What's the next document that you want to discuss?</li><li>A. It is an e-mail string between Medical</li></ul>
2 3 4	shortly after the launch of the TVT-Secur, either at the end of 2006 or beginning of 2007, you were introduced to the TVT-Secur through Ethicon's sales representative?  A. Correct.	2 3 4	<ul> <li>A. No.</li> <li>Q. What's the next document that you want to discuss?</li> <li>A. It is an e-mail string between Medical Directors Dr. Robinson, Dr. Arnaud and Dan Smith.</li> </ul>
2 3 4 5	shortly after the launch of the TVT-Secur, either at the end of 2006 or beginning of 2007, you were introduced to the TVT-Secur through Ethicon's sales representative?	2 3 4 5	<ul><li>A. No.</li><li>Q. What's the next document that you want to discuss?</li><li>A. It is an e-mail string between Medical</li></ul>
2 3 4 5 6	shortly after the launch of the TVT-Secur, either at the end of 2006 or beginning of 2007, you were introduced to the TVT-Secur through Ethicon's sales representative?  A. Correct.  MR. SNELL: Object. BY MR. THORNBURGH:	2 3 4 5 6	<ul> <li>A. No.</li> <li>Q. What's the next document that you want to discuss?</li> <li>A. It is an e-mail string between Medical Directors Dr. Robinson, Dr. Arnaud and Dan Smith.</li> <li>Q. And what is the exhibit number, if you can identify that for the ladies and gentlemen of</li> </ul>
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2 3 4 5 6 7 8 9	shortly after the launch of the TVT-Secur, either at the end of 2006 or beginning of 2007, you were introduced to the TVT-Secur through Ethicon's sales representative?  A. Correct.  MR. SNELL: Object.  BY MR. THORNBURGH:  Q. And did Ethicon sales representative ever inform you that Ethicon's internal first human interim data showed 60% complication rate or 30%	2 3 4 5 6 7 8 9	<ul> <li>A. No.</li> <li>Q. What's the next document that you want to discuss?</li> <li>A. It is an e-mail string between Medical Directors Dr. Robinson, Dr. Arnaud and Dan Smith.</li> <li>Q. And what is the exhibit number, if you can identify that for the ladies and gentlemen of the jury?</li> <li>A. P0619.</li> <li>Q. And can you describe to the ladies and</li> </ul>
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	shortly after the launch of the TVT-Secur, either at the end of 2006 or beginning of 2007, you were introduced to the TVT-Secur through Ethicon's sales representative?  A. Correct. MR. SNELL: Object. BY MR. THORNBURGH: Q. And did Ethicon sales representative ever inform you that Ethicon's internal first human interim data showed 60% complication rate or 30% failure rate? A. No. Q. Did Ethicon ever through its sales representative when she met with you at the end of 2006 or 2007 ever inform you that physicians around the world were experiencing problems with the efficacy of the TVT-Secur device? MR. SNELL: Object.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. No. Q. What's the next document that you want to discuss? A. It is an e-mail string between Medical Directors Dr. Robinson, Dr. Arnaud and Dan Smith. Q. And what is the exhibit number, if you can identify that for the ladies and gentlemen of the jury? A. P0619. Q. And can you describe to the ladies and gentlemen of the jury what P619 is? A. It is an e-mail string from Medical Directors and also Dan Smith, who was the lead engineer and also co-inventor of the TVT-Secur, regarding putting together what was called a cookbook to help physicians overcome their difficulties with implanting the device and in order to try to improve the success rate.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	shortly after the launch of the TVT-Secur, either at the end of 2006 or beginning of 2007, you were introduced to the TVT-Secur through Ethicon's sales representative?  A. Correct. MR. SNELL: Object. BY MR. THORNBURGH: Q. And did Ethicon sales representative ever inform you that Ethicon's internal first human interim data showed 60% complication rate or 30% failure rate? A. No. Q. Did Ethicon ever through its sales representative when she met with you at the end of 2006 or 2007 ever inform you that physicians around the world were experiencing problems with the efficacy of the TVT-Secur device? MR. SNELL: Object. BY THE WITNESS: A. No. BY MR. THORNBURGH: Q. Is that the type of information that is important to implanting physicians?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. No. Q. What's the next document that you want to discuss? A. It is an e-mail string between Medical Directors Dr. Robinson, Dr. Arnaud and Dan Smith. Q. And what is the exhibit number, if you can identify that for the ladies and gentlemen of the jury? A. P0619. Q. And can you describe to the ladies and gentlemen of the jury what P619 is? A. It is an e-mail string from Medical Directors and also Dan Smith, who was the lead engineer and also co-inventor of the TVT-Secur, regarding putting together what was called a cookbook to help physicians overcome their difficulties with implanting the device and in order to try to improve the success rate.  What this document demonstrates is that the Instructions for Use was defective because it could not be used by a physician to effectively,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	shortly after the launch of the TVT-Secur, either at the end of 2006 or beginning of 2007, you were introduced to the TVT-Secur through Ethicon's sales representative?  A. Correct. MR. SNELL: Object. BY MR. THORNBURGH: Q. And did Ethicon sales representative ever inform you that Ethicon's internal first human interim data showed 60% complication rate or 30% failure rate? A. No. Q. Did Ethicon ever through its sales representative when she met with you at the end of 2006 or 2007 ever inform you that physicians around the world were experiencing problems with the efficacy of the TVT-Secur device? MR. SNELL: Object. BY THE WITNESS: A. No. BY MR. THORNBURGH: Q. Is that the type of information that is	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. No. Q. What's the next document that you want to discuss? A. It is an e-mail string between Medical Directors Dr. Robinson, Dr. Arnaud and Dan Smith. Q. And what is the exhibit number, if you can identify that for the ladies and gentlemen of the jury? A. P0619. Q. And can you describe to the ladies and gentlemen of the jury what P619 is? A. It is an e-mail string from Medical Directors and also Dan Smith, who was the lead engineer and also co-inventor of the TVT-Secur, regarding putting together what was called a cookbook to help physicians overcome their difficulties with implanting the device and in order to try to improve the success rate.  What this document demonstrates is that the Instructions for Use was defective because it could not be used by a physician to effectively, accurately and reliably insert the TVT-Secur

	Page 302		Page 304
1	to strike.	1	December 2006. They are already having discussions
2	BY MR. THORNBURGH:	2	about trying to put a reference guide or what's
3	Q. So, what is the significance, if	3	called a cookbook to help doctors place the device
4	anything, of Exhibit P619 to your opinions?	4	safely, effectively or reliably in women because
5	A. It demonstrates that the IFU is	5	the Instructions for Use was not adequate in order
6	defective.	6	to accomplish that.
7	Q. Now, Doctor, I thought you testified	7	Q. Do you have an opinion whether or not
8	that Ethicon had performed design validations to	8	Ethicon should have or could have strike that.
9	validate the information and instructions they were	9	Do you have an opinion whether or not
10	providing to physicians in the TVT-Secur IFU?	10	Ethicon could have strike that.
11	MR. SNELL: Object; leading.	11	Do you have an opinion whether or not
12	BY THE WITNESS:	12	Ethicon could have slowed down the launch of this
13	A. Yes.	13	product, taken its time in design validation to
14	BY MR. THORNBURGH:	14	provide more accurate, clear information in its
15	Q. Is it correct or incorrect that Ethicon	15	IFU?
16	performed design validations to determine the	16	MR. SNELL: Objection.
17	validity and accuracy of the information they were	17	BY THE WITNESS:
18	providing concerning the proper implantation	18	A. Yes.
19	technique to be used when implanting patients with	19	BY MR. THORNBURGH:
20	the TVT-Secur device?	20	Q. What's that opinion?
21	A. Yes.	21	MR. SNELL: Same.
22	Q. And in this case you just testified a	22	BY THE WITNESS:
23	moment ago that this Exhibit 619 demonstrates that	23	A. That they could have slowed the process
24	the IFU is defective?	24	down.
	Page 303		Page 305
1	A. Correct.	1	BY MR. THORNBURGH:
2	MR. SNELL: Objection; leading.	2	Q. And do you have an opinion whether or
3	BY MR. THORNBURGH:	3	not the defects that you describe with respect to
4	Q. First of all, it would be that the IFU	4	the IFU strike that.
5	was defective, is that correct?	5	Do you have an opinion whether or not
6	A. Correct.	6	the defects you describe with respect to the IFU
7	MR. SNELL: Same objection.	7	were caused by the conduct of Ethicon or its
8	BY MR. THORNBURGH:	8	employees?
9	Q. Because Ethicon is no longer selling the	9	MR. SNELL: Objection; leading.
10	Secur device, is that correct?	10	BY THE WITNESS:
11	MR. SNELL: Same objection.	11	A. I don't understand the question.
12	BY THE WITNESS:	12	BY MR. THORNBURGH:
13	A. Correct.	13	Q. Yeah. Sorry.
14	BY MR. THORNBURGH:	14	Do you have an opinion one way or the
15	Q. Is Ethicon still selling the Secur	15	other how the TVT-Secur IFU became defective?
16	device?	16	MR. SNELL: Objection.
17	MR. SNELL: Object.	17	BY MR. THORNBURGH:
18	BY THE WITNESS:	18	Q. Let me ask a better question.
	A. It is not in the United States.	19	You just testified a moment ago that
19			
19 20	BY MR. THORNBURGH:	20	this document supports your opinion that the
		20 21	TVT-Secur IFU was defective?
20	BY MR. THORNBURGH:		** * *
20 21	BY MR. THORNBURGH: Q. Okay. And how does this exhibit	21	TVT-Secur IFU was defective?

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	Page 306		Page 308
1	MR. SNELL: Objection. Same objection.	1	make its way into the TVT-Secur IFU?
2	BY THE WITNESS:	2	MR. SNELL: Object.
3	A. The TVT-Secur device is inherently	3	BY THE WITNESS:
4	defective. The TVT-Secur IFU is inherently	4	A. No, it did not.
5	defective.	5	BY MR. THORNBURGH:
6	BY MR. THORNBURGH:	6	Q. And is it appropriate do you have an
7	Q. Was there any	7	opinion whether or not it's appropriate for a
8	MR. SNELL: I'm going to move to strike as	8	company to fail to update the Information for Use
9	non-responsive.	9	that they provide with medical devices if they
10	BY MR. THORNBURGH:	10	determine that the Information for Use was
11	Q. You had testified earlier about	11	inaccurate or unclear?
12	Ethicon's concern about getting the TVT-Secur on	12	MR. SNELL: Objection and leading.
13	the market first before its competitors released	13	BY THE WITNESS:
14	their mini-sling. Do you recall that testimony?	14	A. If the Instructions for Use are deemed
15	A. Yes.	15	to be inaccurate or unclear, then the Instructions
16	Q. Do you have an opinion whether or not	16	for Use need to be changed to make it accurate and
17	their decision to move quickly to launch the	17	clear.
18	TVT-Secur product had any or played any role in the	18	BY MR. THORNBURGH:
19	information or the lack of accurate information	19	Q. Could Ethicon have could Ethicon
20	that made its way or failed to make its way into	20	did Ethicon have a choice in whether or not to
21	the TVT-Secur IFU?	21	update the TVT-Secur IFU?
22	MR. SNELL: Object; leading.	22	MR. SNELL: Object.
23	BY THE WITNESS:	23	BY THE WITNESS:
24	A. Yes.	24	A. Yes.
	Dama 207		Dama 200
	Page 307		Page 309
1	BY MR. THORNBURGH:	1	BY MR. THORNBURGH:
2	Q. And what is that opinion?	2	Q. Was it do you have an opinion whether
3	A. That that contributed to the IFU being	3	or not it was appropriate or inappropriate for
4	defective.	4	Ethicon to fail to update its IFU?
5	Q. All right. Now, what part of	_	
6		5	MR. SNELL: Object and leading.
	Exhibit 619 support your opinions?	6	BY THE WITNESS:
7	MR. SNELL: Object.	6 7	BY THE WITNESS:  A. It was inappropriate to not update the
7 8	MR. SNELL: Object. BY THE WITNESS:	6 7 8	BY THE WITNESS:  A. It was inappropriate to not update the IFU.
7 8 9	MR. SNELL: Object. BY THE WITNESS: A. This e-mail string goes through a	6 7 8 9	BY THE WITNESS:  A. It was inappropriate to not update the IFU. BY MR. THORNBURGH:
7 8 9 10	MR. SNELL: Object. BY THE WITNESS: A. This e-mail string goes through a discussion between Medical Directors and Dan Smith	6 7 8 9 10	BY THE WITNESS:  A. It was inappropriate to not update the IFU. BY MR. THORNBURGH: Q. Why is that?
7 8 9 10 11	MR. SNELL: Object. BY THE WITNESS: A. This e-mail string goes through a discussion between Medical Directors and Dan Smith regarding that the cookbook was different from the	6 7 8 9 10 11	BY THE WITNESS:  A. It was inappropriate to not update the IFU.  BY MR. THORNBURGH:  Q. Why is that?  A. Because if the IFU is defective, it
7 8 9 10 11	MR. SNELL: Object. BY THE WITNESS: A. This e-mail string goes through a discussion between Medical Directors and Dan Smith regarding that the cookbook was different from the Instructions for Use; that if they decide to do a	6 7 8 9 10 11 12	BY THE WITNESS:  A. It was inappropriate to not update the IFU.  BY MR. THORNBURGH:  Q. Why is that?  A. Because if the IFU is defective, it needs to be changed to make it not defective or the
7 8 9 10 11 12 13	MR. SNELL: Object.  BY THE WITNESS:  A. This e-mail string goes through a discussion between Medical Directors and Dan Smith regarding that the cookbook was different from the Instructions for Use; that if they decide to do a cookbook, they would need to validate a new IFU,	6 7 8 9 10 11 12 13	BY THE WITNESS:  A. It was inappropriate to not update the IFU.  BY MR. THORNBURGH:  Q. Why is that?  A. Because if the IFU is defective, it needs to be changed to make it not defective or the product needs to be removed from the market.
7 8 9 10 11 12 13	MR. SNELL: Object.  BY THE WITNESS:  A. This e-mail string goes through a discussion between Medical Directors and Dan Smith regarding that the cookbook was different from the Instructions for Use; that if they decide to do a cookbook, they would need to validate a new IFU, which a cookbook cannot do.	6 7 8 9 10 11 12 13 14	BY THE WITNESS:  A. It was inappropriate to not update the IFU. BY MR. THORNBURGH: Q. Why is that? A. Because if the IFU is defective, it needs to be changed to make it not defective or the product needs to be removed from the market. Q. And if we turn to ETH.MESH.01000734 of
7 8 9 10 11 12 13 14	MR. SNELL: Object.  BY THE WITNESS:  A. This e-mail string goes through a discussion between Medical Directors and Dan Smith regarding that the cookbook was different from the Instructions for Use; that if they decide to do a cookbook, they would need to validate a new IFU, which a cookbook cannot do.  Q. Now, did Ethicon ever	6 7 8 9 10 11 12 13 14 15	BY THE WITNESS:  A. It was inappropriate to not update the IFU. BY MR. THORNBURGH: Q. Why is that? A. Because if the IFU is defective, it needs to be changed to make it not defective or the product needs to be removed from the market. Q. And if we turn to ETH.MESH.01000734 of Exhibit 619, there's an e-mail from Dan Smith to
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7 8 9 10 11 12 13 14 15 16	MR. SNELL: Object.  BY THE WITNESS:  A. This e-mail string goes through a discussion between Medical Directors and Dan Smith regarding that the cookbook was different from the Instructions for Use; that if they decide to do a cookbook, they would need to validate a new IFU, which a cookbook cannot do.  Q. Now, did Ethicon ever  MR. SNELL: I'm sorry. Object. Move to strike. Reading. Go ahead.	6 7 8 9 10 11 12 13 14 15 16	BY THE WITNESS:  A. It was inappropriate to not update the IFU. BY MR. THORNBURGH: Q. Why is that? A. Because if the IFU is defective, it needs to be changed to make it not defective or the product needs to be removed from the market. Q. And if we turn to ETH.MESH.01000734 of Exhibit 619, there's an e-mail from Dan Smith to Axel. Do you see that?
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7 8 9 10 11 12 13 14 15 16 17	MR. SNELL: Object. BY THE WITNESS:  A. This e-mail string goes through a discussion between Medical Directors and Dan Smith regarding that the cookbook was different from the Instructions for Use; that if they decide to do a cookbook, they would need to validate a new IFU, which a cookbook cannot do.  Q. Now, did Ethicon ever MR. SNELL: I'm sorry. Object. Move to strike. Reading. Go ahead. BY MR. THORNBURGH: Q. Did Ethicon ever update its the TVT-Secur IFU?	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	BY THE WITNESS:  A. It was inappropriate to not update the IFU. BY MR. THORNBURGH: Q. Why is that? A. Because if the IFU is defective, it needs to be changed to make it not defective or the product needs to be removed from the market. Q. And if we turn to ETH.MESH.01000734 of Exhibit 619, there's an e-mail from Dan Smith to Axel. Do you see that? A. Yes. Q. Okay. And what is Dan Smith telling Axel Arnaud concerning the draft IFU that
7 8 9 10 11 12 13 14 15 16 17 18	MR. SNELL: Object. BY THE WITNESS:  A. This e-mail string goes through a discussion between Medical Directors and Dan Smith regarding that the cookbook was different from the Instructions for Use; that if they decide to do a cookbook, they would need to validate a new IFU, which a cookbook cannot do.  Q. Now, did Ethicon ever MR. SNELL: I'm sorry. Object. Move to strike. Reading. Go ahead. BY MR. THORNBURGH: Q. Did Ethicon ever update its the TVT-Secur IFU? A. No, they did not.	6 7 8 9 10 11 12 13 14 15 16 17 18	BY THE WITNESS:  A. It was inappropriate to not update the IFU. BY MR. THORNBURGH: Q. Why is that? A. Because if the IFU is defective, it needs to be changed to make it not defective or the product needs to be removed from the market. Q. And if we turn to ETH.MESH.01000734 of Exhibit 619, there's an e-mail from Dan Smith to Axel. Do you see that? A. Yes. Q. Okay. And what is Dan Smith telling
7 8 9 10 11 12 13 14 15 16 17 18 19 20	MR. SNELL: Object. BY THE WITNESS:  A. This e-mail string goes through a discussion between Medical Directors and Dan Smith regarding that the cookbook was different from the Instructions for Use; that if they decide to do a cookbook, they would need to validate a new IFU, which a cookbook cannot do.  Q. Now, did Ethicon ever MR. SNELL: I'm sorry. Object. Move to strike. Reading. Go ahead. BY MR. THORNBURGH: Q. Did Ethicon ever update its the TVT-Secur IFU?	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	BY THE WITNESS:  A. It was inappropriate to not update the IFU. BY MR. THORNBURGH: Q. Why is that? A. Because if the IFU is defective, it needs to be changed to make it not defective or the product needs to be removed from the market. Q. And if we turn to ETH.MESH.01000734 of Exhibit 619, there's an e-mail from Dan Smith to Axel. Do you see that? A. Yes. Q. Okay. And what is Dan Smith telling Axel Arnaud concerning the draft IFU that
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MR. SNELL: Object. BY THE WITNESS:  A. This e-mail string goes through a discussion between Medical Directors and Dan Smith regarding that the cookbook was different from the Instructions for Use; that if they decide to do a cookbook, they would need to validate a new IFU, which a cookbook cannot do.  Q. Now, did Ethicon ever MR. SNELL: I'm sorry. Object. Move to strike. Reading. Go ahead. BY MR. THORNBURGH: Q. Did Ethicon ever update its the TVT-Secur IFU? A. No, they did not.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY THE WITNESS:  A. It was inappropriate to not update the IFU. BY MR. THORNBURGH: Q. Why is that? A. Because if the IFU is defective, it needs to be changed to make it not defective or the product needs to be removed from the market. Q. And if we turn to ETH.MESH.01000734 of Exhibit 619, there's an e-mail from Dan Smith to Axel. Do you see that? A. Yes. Q. Okay. And what is Dan Smith telling Axel Arnaud concerning the draft IFU that Dr. Arnaud had distributed or sent to Dan Smith and

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difficulties with this document. I don't know where to start. I have not even looked at the U.  It cannot go out like this, nor do I believe this is what is needed. Everything in the blue shade is either wrong or needs much work to align with the Instructions for Use and I'm not writing another Instructions for Use. The Instructions for Use contains detailed information that they must follow. This document should be a cheat sheet and not another IFU."  Q. Now, Axel Arnaud is the Medical Director?  A. Yes.  Q. And Dan Smith is an engineer?  A. Correct.  Q. Based on your review of the internal documents, did Dan Smith have any formal medical training?  MR. SNELL: Objection.  BY MR. THORNBURGH:  Q. And, now, if you go down to the next paragraph, there's a statement by Dr. Axel Arnaud that "The answers to the surgeon's questions not being in the IFU, there is a need for what made the reproducibility and success of both TVT and TVT is encotobook."  He goes on to write, "The documents I sent you are based on the opinion of numerous European experts and pearls from U.S. surgeons.'  MR. SNELL: Objection; leading.  BY THE WITNESS:  A. That the IFU is defective because it there are surgeons' questions that are not answere by the Instructions for Use.  BY THE WITNESS:  A. No.  BY MR. THORNBURGH:  Q. And how does Dr. Dan Smith respond?  A. Mr  Q. I'm sorry. Strike that.  How does Mr. Dan Smith, the engineer at		Page 310		Page 312
where to start. I have not even looked at the U.  It camon go out like this, nor do I believe this is is what is needed. Everything in the blue shade is either wrong or needs much work to align with the Instructions for Use and I'm not writing another Instructions for Use and I'm not writing another Instructions for Use. The Instructions for Use contains detailed information that they must follow. This document should be a cheat sheet and no not morter IFU."  10 Gollow. This document should be a cheat sheet and not not morter IFU."  11 not another IFU."  12 Q. Now, Axel Arnaud is the Medical 11 not another IFU."  13 Director? 13 What does that statement by Dr. Amaud indicate to you? 14 A. Yes. 15 Q. And Dan Smith is an engineer? 15 MR. SNELL: Objection. 18 What does that statement by Dr. Amaud indicate to you? 18 MR. SNELL: Objection. 18 What does that statement by Dr. Amaud indicate to you? 19 MR. SNELL: Objection. 18 What Have any formal medical 19 training? 19 What does that statement by Dr. Amaud indicate to you? 19 MR. SNELL: Objection; leading. 19 What does that statement by Dr. Amaud indicate to you? 19 MR. SNELL: Objection; leading. 19 What does that statement by Dr. Amaud indicate to you? 19 MR. SNELL: Objection; leading. 19 What does that statement by Dr. Amaud indicate to you? 19 MR. SNELL: Objection; leading. 19 What does that statement by Dr. Amaud indicate to you? 19 MR. SNELL: Objection; leading. 19 What does that statement by Dr. Amaud indicate to you? 19 MR. SNELL: Objection; leading. 19 What does that statement by Dr. Amaud indicate to you? 19 MR. SNELL: Objection; leading. 19 What does that statement by Dr. Amaud indicate to you? 19 MR. SNELL: Object and leading. 19 What manufacture is the rear surgeons' questions that are not answere by the instructions for Use. 19 What manufacture is the wint are are surgeons' questions that are not answere by the instructions for Use. 19 What manufacture is the first warm of the prevention of the statement of the whot was a statement of the prevention of t	1	A. He is stating, "I have major	1	They have a hard time to achieve consistently good
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what is needed or not, when many of our customers 21 BY MR. THORNBURGH:			1	
·			1	
22 unemiseives do not know after their initial 22 Q. Do you have an opinion whether or not				
22			1	
experience" "our customers themselves still do 23 Ethicon could have done that?			1	
not know after their initial experience with Secur. 24 A. Yes, I do have an opinion.			. 0.4	A Vec I do have an opinion

79 (Pages 310 to 313)

1 Q. Do you have an opinion whether or not 2 Ethicon should have done that? 3 A. Yes, I have an opinion. 4 Q. And what are those opinions? 5 A. They could have done that and should 6 have done that. 7 Q. Is there anything else you'd like to 8 discuss with respect to Exhibit 619? 1 included and/or stop for a 2 that could compromise the 3 A. That could compromise the 4 Dr. Buchon or Xavier Buc 5 A. That Ethicon was 6 information with doctors. 7 stating that they would rath 8 that would compromise the	future." does that statement by
3 A. Yes, I have an opinion. 4 Q. And what are those opinions? 5 A. They could have done that and should 6 have done that. 7 Q. Is there anything else you'd like to 3 Q. And what opinion 4 Dr. Buchon or Xavier Buc 5 A. That Ethicon was 6 information with doctors. 7 stating that they would rat	does that statement by
4 Q. And what are those opinions? 4 Dr. Buchon or Xavier Buc 5 A. They could have done that and should 5 A. That Ethicon was 6 have done that. 6 information with doctors. 7 Q. Is there anything else you'd like to 7 stating that they would rat	•
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6 have done that. 6 information with doctors. 7 Q. Is there anything else you'd like to 7 stating that they would rate	
7 Q. Is there anything else you'd like to 7 stating that they would rate	not sharing negative
	It is this e-mail is
8 discuss with respect to Exhibit 619? 8 that would compromise the	her stop publication
and would compromise the	e future of the TVT-Secur.
9 A. No. 9 Q. And is it appropria	ate for medical device
10 Q. What's the next document you'd like to 10 companies to attempt to st	op medical publications
11 discuss? 11 concerning the safety of the	eir products?
12 A. It is an e-mail on from January 16, 12 A. No.	
13 2007 from key Ethicon employees, including Harel 13 Q. Is it appropriate for	or companies to
14 Gadot, Axel Arnaud, discussing the French TVT-Secur 14 attempt to manipulate data	related to safety or
15 data. 15 efficacy of their permanen	t medical device
16 Q. And what's the exhibit number? 16 products?	
17 A. P1100. 17 MR. SNELL: Object.	
18 Q. And what, if anything, is significant to 18 BY THE WITNESS:	
19 your opinions with respect to Exhibit 1100? 19 A. No.	
20 A. This e-mail also confirms that doctors 20 BY MR. THORNBURGH	<b>[:</b>
21 in France were having concerns about the efficacy 21 Q. So, if we just break	k this down really
22 of the TVT-Secur. 22 quick, on page on the fit	rst page of this
Q. Can you direct us to the part or parts 23 exhibit, the response to Fa	brice's concerns, it
24 of this exhibit that you rely on for to support 24 states, "This is for sure a b	ig concern and I would
Page 315	
1 your opinion? 1 recommend we have your s 2 A. Yes. "I was with Dr. Jacquetin today. 2 potentially review the patie	
3 He is currently collecting data on Secur. My main 3 and/or stop for a while such	
4 concern is the outcome of their data, the success 4 could compromise the future	•
5 rate following TVT-Secur" excuse me 5 truth but to make sure it has	
6 "implementation is way below TVT-O or TVT around 80 6 in terms of procedure and in	
7 to 85%." 7 think? We may even ask ac	
8 Q. And what, if anything, is significant 8 great support?"	ivice moint mad who is a
9 about that part of this e-mail? 9 Did I read that correct	ctly?
10 MR. SNELL: Objection. 10 MR. SNELL: Object an	=
11 BY THE WITNESS: 11 BY THE WITNESS:	a reading.
12 A. It is confirmed it confirms that 12 A. Yes.	
13 doctors are having concerns about the success rate  13 BY MR. THORNBURGH:	
14 for the TVT-Secur. 14 Q. Is it ever okay for a	
15 BY MR. THORNBURGH: 15 actually review what types	
16 Q. And is there anything else are there 16 strike that.	Laurence of Hillo
27 any other portions of this exhibit that you rely on 27 Is it ever appropriate	for a company
18 to support your opinions? 18 like Ethicon to go and revie	
1 19 A Yes 19 determine whether or not the	=
19 A. Yes. 19 determine whether or not the 20 O. Can you direct us there? 20 appropriately including the	
20 Q. Can you direct us there? 20 appropriately including the	
20 Q. Can you direct us there? 20 appropriately including the 21 A. It is the follow-up to that. 21 MR. SNELL: Objection	1.
20 Q. Can you direct us there? 20 appropriately including the 21 A. It is the follow-up to that. 21 MR. SNELL: Objection 22 "This is for sure a big concern. I 22 BY MR. THORNBURGH:	1.
20 Q. Can you direct us there? 20 appropriately including the 21 A. It is the follow-up to that. 21 MR. SNELL: Objection	1.

80 (Pages 314 to 317)

	Page 318		Page 320
1	Are there ways to manipulate scientific	1	manager, regarding the incontinence platform,
2	data?	2	worldwide marketing team update, August 19, 2007,
3	A. Yes.	3	if I believe.
4	Q. What are some of those ways?	4	Q. And what what, if anything what,
5	MR. SNELL: Objection.	5	if anything, did you rely on from this exhibit to
6	BY THE WITNESS:	6	support your opinions?
7	A. Fail to include patients that have an	7	A. This document supports my opinions
8	outcome that is not favorable to the conclusions	8	regarding the defects associated with the TVT-Secur
9	that you are looking to draw.	9	that were leading to complications. It also
10	BY MR. THORNBURGH:	10	supports the my opinions that the Instructions
11	Q. Is it appropriate for medical device	11	for Use was defective and that even a cookbook
12	companies like Ethicon to interfere with the	12	could not help with the defects of the Instructions
13	publication of safety data?	13	for Use, that the training associated with the
14	MR. SNELL: Objection.	14	TVT-Secur device was not adequate and there was no
15	BY THE WITNESS:	15	clinical data at the time of launch of the
16	A. No.	16	TVT-Secur product.
17	BY MR. THORNBURGH:	17	Q. Can you walk us through Exhibit P0784
18	Q. Why not?	18	and identify what parts of this exhibit support
19	A. Because that data is important for	19	your opinions and describe for the ladies and
20	doctors to know so they can have the full view of	20	gentlemen of the jury what significance, if any,
21	what the experience is with scientists and other	21	this document has for those opinions?
22	doctors so they can make an informed decision about	22	A. On TVT-Secur year-to-date findings. It
23	using a product.	23	would be the I think about the 10th or so page in.
24	Q. And does the interference of medical	24	"Main Difficulties and Complications.
1	device companies like Ethicon and Johnson & Johnson	1	Insertion difficulties, releasing difficulties,
2	with respect to scientific publications impact the	2	fixation tips not staying in place."
3	knowledge of physicians in a negative way	3	One of the defects that I described is
4	concerning products that they may choose to implant	4	that the fleece tips did not did not hold the
5	in their patients?	5	device in place so the device the stiff, rigid
6	MR. SNELL: Objection and leading.	6	mesh would migrate and move which would increase
7	BY THE WITNESS:	7	the failure rate and also increase the
8	A. Yes.	8	complications associated with the device.
9	BY MR. THORNBURGH:	9	"Bladder perforation, excessive bleeding
10	Q. And how so?	10	and failures in tensioning," which is a defect in
11	MR. SNELL: Same.	11	the Instructions for Use, trying to describe for
12	BY THE WITNESS:	12	physicians how to tension.
13	A. If information is not being accurate	13	On the next page, under No. 7, "Not
14	information is not being put in the literature,	14	well-defined cookbook procedures" "cookbook
15	doctors cannot have knowledge of that information	15	procedure leads to differences in technique between
16	in order to be able to share it with patients in	16	surgeons. The learning curve is longer than
17	order to determine what is the best therapy for the	17	expected. There's a lack of the right training.
18	patient.	18	Lack of well-known Key Opinion Leaders advocating
19	Q. Is there anything else relevant with	19	for the Secur and lack of clinical data."
20	respect to Exhibit 1100 that you want to discuss?	20	Q. Let me just talk about No. 10 really
	A. No.	21	quick.
		1 21	
21		22	We had briefly discussed Professor
21 22	Q. What's the next document?	22	We had briefly discussed Professor Nilsson and Professor Artibani Do you recall
21		22 23 24	We had briefly discussed Professor Nilsson and Professor Artibani. Do you recall that?

81 (Pages 318 to 321)

İ	Page 322		Page 324
1	A. Yes.	1	document, slide 15.
2	Q. And do you know whether or not	2	MR. THORNBURGH: No, he wants to go here.
3	Dr. Nilsson or Dr. Artibani had any involvement in	3	MR. BODYZIAK: This is page 20 of the
4	the First Human Use Study?	4	document. Is that the correct one?
5	A. If I recall, at least Dr. Nilsson was	5	MR. THORNBURGH: For the record it's page 20
6	part of the First Human Use Study.	6	of the document.
7	Q. Okay. And by the date or drafting of	7	BY MR. THORNBURGH:
8	this exhibit of August 19, 2007, what does the	8	Q. And how does page 20 of Exhibit 784
9	statement number in No. 10 reflect with respect to	9	support your opinions, if at all?
10	Dr. Nilsson and Dr. Artibani?	10	A. It shows the learning curve, that it
11	A. They are not support	11	takes a significant number of procedures to, at
12	MR. SNELL: Object. Go ahead.	12	least at six weeks of follow-up, which is an
13	BY THE WITNESS:	13	exceedingly short follow-up, get an adequate
14	A. They are not supporting the TVT-Secur.	14	efficacy from the product.
15	BY MR. THORNBURGH:	15	Q. Okay. So, let's break this down for a
16	O. And we talked earlier about Dr. Nilsson	16	little bit.
17	and Dr. Artibani and their concerns with Ethicon	17	Dr. Artibani discusses the success rate
18	launching the TVT-Secur product without conducting	18	of the first 25 patients.
19	randomized controlled trials.	19	Do you see that?
20	Do you recall that?	20	MR. SNELL: Objection.
21	A. Yes.	21	BY THE WITNESS:
22	A. Tes. MR. SNELL: Object and leading.	22	
23	BY MR. THORNBURGH:	23	A. Dr. Lucente. BY MR. THORNBURGH:
		24	
24	Q. Okay. And let me ask you this question:	24	Q. Dr. Lucente. Strike that.
	Page 323		Page 325
1	Do you have an opinion whether or not Dr. Nilsson	1	So, on page 20 is Dr. Lucente discussing
2	and Dr. Artibani were correct in their concern	2	his experience at six weeks follow-up?
3	about releasing the TVT-Secur on the market without	3	A. Correct.
4	first conducting the appropriate randomized	4	Q. And in the first 25 patients what were
5	controlled trials?	5	Dr. Lucente's results?
6	MR. SNELL: Objection.	6	A. The failure rate was 40%.
7	BY THE WITNESS:	7	Q. And is that an appropriate failure rate?
8	A. They were correct.	8	A. No, it is not.
9	BY MR. THORNBURGH:	9	Q. Now, Dr. Artibani then has the "First 77
10	Q. And do you is there anything else	10	Patients," and he writes that there were
11	with respect to this page of the slide that's	11	MR. SNELL: You got to reread do it. You keep
12	relevant to your opinions?	12	saying Artibani.
13	A. That other Key Opinion Leaders are	13	BY MR. THORNBURGH:
14	insisting on clinical data first.	14	Q. Dr. Lucente then has the results for his
15	Q. Okay. Can you direct us to the next	15	first 77 patients.
16	part of this exhibit that you rely on would support	16	Do you see that?
17	your opinions?	17	A. Yes.
18	A. Yes. The "TVT-Secur, Lucente experience	18	Q. And what does Dr. Lucente report?
19	at 6 weeks follow-up."	19	A. A 31% failure rate.
	MR. THORNBURGH: And let's go ahead and turn	20	Q. And what does Dr. Lucente report for all
20	THE THORESONOIL AND ICES BO AIRCAU AND HALL		136 patients with respect to failure rate?
20 21	there Tom	」つし	
21	there, Tom.	21	
21 22	Tom, what page is that shown for the	22	A. A 23% failure rate.
21	•		

82 (Pages 322 to 325)

	Page 326		Page 328
1	A. Yes.	1	rely on this document?
2	Q. And did you review and rely on	2	A. Yes.
3	Dr. Lucente's other data concerning his patients?	3	Q. And what is this document?
4	A. Yes.	4	A. It is an e-mail from Stephanie Molden,
5	Q. And who is Dr. Lucente?	5	which is a she is a partner of Dr. Lucente, and
6	A. Dr. Lucente is a well-known	6	it's regarding the TVT-Secur, their TVT-Secur data.
7	urogynecological surgeon, Key Opinion Leader for	7	Q. And you say she was a partner with
8	Ethicon.	8	Dr. Lucente. Like Dr. Lucente, do you know whether
9	Q. And did Dr. Lucente have any involvement	9	or not she is a urogynecologist?
10	in the First Human Use Study?	10	A. Yes.
11	A. Yes.	11	Q. And does this exhibit, an e-mail
12	Q. What involvement, if any, did	12	concerning Dr. Lucente, support any of your
13	Dr. Lucente have there?	13	opinions?
14	A. He was one of the surgeons that was	14	A. Yes.
15	involved in the First Human Use Study.	15	Q. What opinions does it support?
16	Q. Okay. And what's the next document you	16	A. That the design characteristics of the
17	want to discuss?	17	TVT-Secur device makes it unreasonably ineffective.
18	A. The next page, the "TVT-Secur take-home	18	Q. Okay. And if we look at what section
19	message."	19	of this e-mail specifically supports those
20	MR. THORNBURGH: Hold on one second,	20	opinions?
21	Dr. Rosenzweig.	21	A. The bottom half of the e-mail string is
22	BY MR. THORNBURGH:	22	a representation of Dr. Lucente's data. We saw in
23	Q. I want to just go back a little bit to	23	the previous slide that at six weeks he was
24	page 20 of this exhibit, Exhibit 784, and talk to	24	reporting a 22% failure rate. Here he has a 14%
	Page 327		Page 329
1			
	you some more about Dr. Lucente.	1	failure rate at six weeks.
2	you some more about Dr. Lucente.  And I'll represent to you that the	1 2	failure rate at six weeks.  However, when they look at their
	-		
2	And I'll represent to you that the	2	However, when they look at their
2	And I'll represent to you that the that the metadata on Exhibit 784 shows that it was	2 3	However, when they look at their patients out to one year, their failure rate is
2 3 4	And I'll represent to you that the that the metadata on Exhibit 784 shows that it was created August 19 of 2007.	2 3 4	However, when they look at their patients out to one year, their failure rate is over 60%.
2 3 4 5	And I'll represent to you that the that the metadata on Exhibit 784 shows that it was created August 19 of 2007. A. Okay.	2 3 4 5	However, when they look at their patients out to one year, their failure rate is over 60%.  Q. Now, what does Stephanie Molden write
2 3 4 5 6	And I'll represent to you that the that the metadata on Exhibit 784 shows that it was created August 19 of 2007.  A. Okay.  Q. Okay. Did you also go ahead and mark	2 3 4 5 6	However, when they look at their patients out to one year, their failure rate is over 60%.  Q. Now, what does Stephanie Molden write with respect to these results?
2 3 4 5 6 7	And I'll represent to you that the that the metadata on Exhibit 784 shows that it was created August 19 of 2007.  A. Okay.  Q. Okay. Did you also go ahead and mark actually as Exhibit P1437, and I think you may have	2 3 4 5 6 7	However, when they look at their patients out to one year, their failure rate is over 60%.  Q. Now, what does Stephanie Molden write with respect to these results?  A. "I'm not really looking too much at one
2 3 4 5 6 7 8	And I'll represent to you that the that the metadata on Exhibit 784 shows that it was created August 19 of 2007.  A. Okay.  Q. Okay. Did you also go ahead and mark actually as Exhibit P1437, and I think you may have it in your binder.	2 3 4 5 6 7 8	However, when they look at their patients out to one year, their failure rate is over 60%.  Q. Now, what does Stephanie Molden write with respect to these results?  A. "I'm not really looking too much at one year patients since we know they are worse. But
2 3 4 5 6 7 8 9	And I'll represent to you that the that the metadata on Exhibit 784 shows that it was created August 19 of 2007.  A. Okay.  Q. Okay. Did you also go ahead and mark actually as Exhibit P1437, and I think you may have it in your binder.  A. I would not know where it is.	2 3 4 5 6 7 8	However, when they look at their patients out to one year, their failure rate is over 60%.  Q. Now, what does Stephanie Molden write with respect to these results?  A. "I'm not really looking too much at one year patients since we know they are worse. But excluding those, our rates are steadily decreasing
2 3 4 5 6 7 8 9	And I'll represent to you that the that the metadata on Exhibit 784 shows that it was created August 19 of 2007.  A. Okay. Q. Okay. Did you also go ahead and mark actually as Exhibit P1437, and I think you may have it in your binder.  A. I would not know where it is. MR. THORNBURGH: Here. Let me just hand	2 3 4 5 6 7 8 9	However, when they look at their patients out to one year, their failure rate is over 60%.  Q. Now, what does Stephanie Molden write with respect to these results?  A. "I'm not really looking too much at one year patients since we know they are worse. But excluding those, our rates are steadily decreasing with longer follow-up in a cohort of 247 patients."
2 3 4 5 6 7 8 9 10	And I'll represent to you that the that the metadata on Exhibit 784 shows that it was created August 19 of 2007.  A. Okay.  Q. Okay. Did you also go ahead and mark actually as Exhibit P1437, and I think you may have it in your binder.  A. I would not know where it is. MR. THORNBURGH: Here. Let me just hand you go ahead and pull up 1437.	2 3 4 5 6 7 8 9 10	However, when they look at their patients out to one year, their failure rate is over 60%.  Q. Now, what does Stephanie Molden write with respect to these results?  A. "I'm not really looking too much at one year patients since we know they are worse. But excluding those, our rates are steadily decreasing with longer follow-up in a cohort of 247 patients."  Q. And she goes on to say, "Not sure why
2 3 4 5 6 7 8 9 10 11	And I'll represent to you that the that the metadata on Exhibit 784 shows that it was created August 19 of 2007.  A. Okay. Q. Okay. Did you also go ahead and mark actually as Exhibit P1437, and I think you may have it in your binder.  A. I would not know where it is. MR. THORNBURGH: Here. Let me just hand you go ahead and pull up 1437. BY THE WITNESS:	2 3 4 5 6 7 8 9 10 11 12	However, when they look at their patients out to one year, their failure rate is over 60%.  Q. Now, what does Stephanie Molden write with respect to these results?  A. "I'm not really looking too much at one year patients since we know they are worse. But excluding those, our rates are steadily decreasing with longer follow-up in a cohort of 247 patients."  Q. And she goes on to say, "Not sure why the 3 to 4 month rate is lower than the 6 months,
2 3 4 5 6 7 8 9 10 11 12 13	And I'll represent to you that the that the metadata on Exhibit 784 shows that it was created August 19 of 2007.  A. Okay. Q. Okay. Did you also go ahead and mark actually as Exhibit P1437, and I think you may have it in your binder.  A. I would not know where it is. MR. THORNBURGH: Here. Let me just hand you go ahead and pull up 1437. BY THE WITNESS: A. Okay. I found it.	2 3 4 5 6 7 8 9 10 11 12	However, when they look at their patients out to one year, their failure rate is over 60%.  Q. Now, what does Stephanie Molden write with respect to these results?  A. "I'm not really looking too much at one year patients since we know they are worse. But excluding those, our rates are steadily decreasing with longer follow-up in a cohort of 247 patients."  Q. And she goes on to say, "Not sure why the 3 to 4 month rate is lower than the 6 months, but Secur appears not to hold up with time."
2 3 4 5 6 7 8 9 10 11 12 13 14	And I'll represent to you that the that the metadata on Exhibit 784 shows that it was created August 19 of 2007.  A. Okay. Q. Okay. Did you also go ahead and mark actually as Exhibit P1437, and I think you may have it in your binder. A. I would not know where it is. MR. THORNBURGH: Here. Let me just hand you go ahead and pull up 1437. BY THE WITNESS: A. Okay. I found it. BY MR. THORNBURGH:	2 3 4 5 6 7 8 9 10 11 12 13 14	However, when they look at their patients out to one year, their failure rate is over 60%.  Q. Now, what does Stephanie Molden write with respect to these results?  A. "I'm not really looking too much at one year patients since we know they are worse. But excluding those, our rates are steadily decreasing with longer follow-up in a cohort of 247 patients."  Q. And she goes on to say, "Not sure why the 3 to 4 month rate is lower than the 6 months, but Secur appears not to hold up with time."  Did I read that correctly?
2 3 4 5 6 7 8 9 10 11 12 13 14	And I'll represent to you that the that the metadata on Exhibit 784 shows that it was created August 19 of 2007.  A. Okay. Q. Okay. Did you also go ahead and mark actually as Exhibit P1437, and I think you may have it in your binder. A. I would not know where it is. MR. THORNBURGH: Here. Let me just hand you go ahead and pull up 1437. BY THE WITNESS: A. Okay. I found it. BY MR. THORNBURGH: Q. Okay. And so we're looking at what	2 3 4 5 6 7 8 9 10 11 12 13 14 15	However, when they look at their patients out to one year, their failure rate is over 60%.  Q. Now, what does Stephanie Molden write with respect to these results?  A. "I'm not really looking too much at one year patients since we know they are worse. But excluding those, our rates are steadily decreasing with longer follow-up in a cohort of 247 patients."  Q. And she goes on to say, "Not sure why the 3 to 4 month rate is lower than the 6 months, but Secur appears not to hold up with time."  Did I read that correctly?  A. Yes.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	And I'll represent to you that the that the metadata on Exhibit 784 shows that it was created August 19 of 2007.  A. Okay. Q. Okay. Did you also go ahead and mark actually as Exhibit P1437, and I think you may have it in your binder.  A. I would not know where it is. MR. THORNBURGH: Here. Let me just hand you go ahead and pull up 1437. BY THE WITNESS: A. Okay. I found it. BY MR. THORNBURGH: Q. Okay. And so we're looking at what is it?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	However, when they look at their patients out to one year, their failure rate is over 60%.  Q. Now, what does Stephanie Molden write with respect to these results?  A. "I'm not really looking too much at one year patients since we know they are worse. But excluding those, our rates are steadily decreasing with longer follow-up in a cohort of 247 patients."  Q. And she goes on to say, "Not sure why the 3 to 4 month rate is lower than the 6 months, but Secur appears not to hold up with time."  Did I read that correctly?  A. Yes.  Q. Does that support any of your opinions?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	And I'll represent to you that the that the metadata on Exhibit 784 shows that it was created August 19 of 2007.  A. Okay. Q. Okay. Did you also go ahead and mark actually as Exhibit P1437, and I think you may have it in your binder.  A. I would not know where it is. MR. THORNBURGH: Here. Let me just hand you go ahead and pull up 1437. BY THE WITNESS: A. Okay. I found it. BY MR. THORNBURGH: Q. Okay. And so we're looking at what is it? A. P1437.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	However, when they look at their patients out to one year, their failure rate is over 60%.  Q. Now, what does Stephanie Molden write with respect to these results?  A. "I'm not really looking too much at one year patients since we know they are worse. But excluding those, our rates are steadily decreasing with longer follow-up in a cohort of 247 patients."  Q. And she goes on to say, "Not sure why the 3 to 4 month rate is lower than the 6 months, but Secur appears not to hold up with time."  Did I read that correctly?  A. Yes.  Q. Does that support any of your opinions?  MR. SNELL: Object; leading.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	And I'll represent to you that the that the metadata on Exhibit 784 shows that it was created August 19 of 2007.  A. Okay. Q. Okay. Did you also go ahead and mark actually as Exhibit P1437, and I think you may have it in your binder. A. I would not know where it is. MR. THORNBURGH: Here. Let me just hand you go ahead and pull up 1437. BY THE WITNESS: A. Okay. I found it. BY MR. THORNBURGH: Q. Okay. And so we're looking at what is it? A. P1437. Q. And that's in your binder? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	However, when they look at their patients out to one year, their failure rate is over 60%.  Q. Now, what does Stephanie Molden write with respect to these results?  A. "I'm not really looking too much at one year patients since we know they are worse. But excluding those, our rates are steadily decreasing with longer follow-up in a cohort of 247 patients."  Q. And she goes on to say, "Not sure why the 3 to 4 month rate is lower than the 6 months, but Secur appears not to hold up with time."  Did I read that correctly?  A. Yes.  Q. Does that support any of your opinions?  MR. SNELL: Object; leading.  BY THE WITNESS:
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	And I'll represent to you that the that the metadata on Exhibit 784 shows that it was created August 19 of 2007.  A. Okay. Q. Okay. Did you also go ahead and mark actually as Exhibit P1437, and I think you may have it in your binder. A. I would not know where it is. MR. THORNBURGH: Here. Let me just hand you go ahead and pull up 1437. BY THE WITNESS: A. Okay. I found it. BY MR. THORNBURGH: Q. Okay. And so we're looking at what is it? A. P1437. Q. And that's in your binder? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	However, when they look at their patients out to one year, their failure rate is over 60%.  Q. Now, what does Stephanie Molden write with respect to these results?  A. "I'm not really looking too much at one year patients since we know they are worse. But excluding those, our rates are steadily decreasing with longer follow-up in a cohort of 247 patients."  Q. And she goes on to say, "Not sure why the 3 to 4 month rate is lower than the 6 months, but Secur appears not to hold up with time."  Did I read that correctly?  A. Yes.  Q. Does that support any of your opinions?  MR. SNELL: Object; leading.  BY THE WITNESS:  A. Yes.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	And I'll represent to you that the that the metadata on Exhibit 784 shows that it was created August 19 of 2007.  A. Okay. Q. Okay. Did you also go ahead and mark actually as Exhibit P1437, and I think you may have it in your binder.  A. I would not know where it is. MR. THORNBURGH: Here. Let me just hand you go ahead and pull up 1437. BY THE WITNESS: A. Okay. I found it. BY MR. THORNBURGH: Q. Okay. And so we're looking at what is it? A. P1437. Q. And that's in your binder? A. Yes. Q. Exhibit 5. Yes. And the tab number is 32?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	However, when they look at their patients out to one year, their failure rate is over 60%.  Q. Now, what does Stephanie Molden write with respect to these results?  A. "I'm not really looking too much at one year patients since we know they are worse. But excluding those, our rates are steadily decreasing with longer follow-up in a cohort of 247 patients."  Q. And she goes on to say, "Not sure why the 3 to 4 month rate is lower than the 6 months, but Secur appears not to hold up with time."  Did I read that correctly?  A. Yes.  Q. Does that support any of your opinions?  MR. SNELL: Object; leading.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:  Q. What about this this statement from
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	And I'll represent to you that the that the metadata on Exhibit 784 shows that it was created August 19 of 2007.  A. Okay. Q. Okay. Did you also go ahead and mark actually as Exhibit P1437, and I think you may have it in your binder.  A. I would not know where it is. MR. THORNBURGH: Here. Let me just hand you go ahead and pull up 1437. BY THE WITNESS: A. Okay. I found it. BY MR. THORNBURGH: Q. Okay. And so we're looking at what is it? A. P1437. Q. And that's in your binder? A. Yes. Q. Exhibit 5. Yes. And the tab number is 32?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	However, when they look at their patients out to one year, their failure rate is over 60%.  Q. Now, what does Stephanie Molden write with respect to these results?  A. "I'm not really looking too much at one year patients since we know they are worse. But excluding those, our rates are steadily decreasing with longer follow-up in a cohort of 247 patients."  Q. And she goes on to say, "Not sure why the 3 to 4 month rate is lower than the 6 months, but Secur appears not to hold up with time."  Did I read that correctly?  A. Yes.  Q. Does that support any of your opinions?  MR. SNELL: Object; leading.  BY THE WITNESS:  A. Yes.  BY MR. THORNBURGH:

83 (Pages 326 to 329)

	Page 330		Page 332
1	characteristics of the device that make it	1	Q. Are those good results, Doctor?
2	unreasonably uneffective to treat stress urinary	2	A. No.
3	incontinence.	3	Q. By by the that three-to-four month
4	Q. Now, Dr. Molden says that when they	4	period, do you have an understanding of whether or
5	exclude the one year strike that.	5	not Dr. Lucente would have overcome the learning
6	Dr. Molden states that "I'm not really	6	curve?
7	looking too much at the one year patients since we	7	MR. SNELL: Objection.
8	know they were worse."	8	BY THE WITNESS:
9	Do you have any understanding as to why	9	A. Yes.
10	they knew the one-year patients would be worse?	10	BY MR. THORNBURGH:
11	MR. SNELL: Objection and leading.	11	Q. And what's that opinion?
12	BY THE WITNESS:	12	A. He would have overcome the learning
13	A. Well, since this is from January of	13	curve.
14	2008, those patients were done before January of	14	Q. Did the learning curve have any impact
15	2007.	15	on the strike that.
16	BY MR. THORNBURGH:	16	Does that does that fact or issue
17	Q. Would that first would those be	17	support any of your opinions and, if so, what
18	the earlier patients?	18	opinions?
19	MR. SNELL: Objection.	19	MR. SNELL: Objection.
20	BY THE WITNESS:	20	BY THE WITNESS:
21	A. Potentially.	21	A. That the TVT-Secur is not effective in
22	BY MR. THORNBURGH:	22	treating stress urinary incontinence. There are
23	Q. Would those patients potentially be part	23	design characteristics that make it unreasonably
24	of the learning curve?	24	ineffective in treating stress urinary
	Page 331		Page 333
1	A. Potentially.	1	incontinence.
2	Q. And if Dr. Molden is she says, even	2	BY MR. THORNBURGH:
3	if we exclude those first patients from the	3	Q. Okay.
4	one-year data, did that have any impact on the	4	MR. SNELL: While they are conferring I will
5	success over time of the TVT-Secur product?	5	put an objection. P1437 not on reliance list.
6	MR. SNELL: Object and leading.	6	MR. THORNBURGH: Yes, it is.
7	BY THE WITNESS:	1 7	MR. SNELL: I know it's on the one you just
0		'	• 0
8	A. No, because the success does not hold up	8	served, but it wasn't on the one that led to him
9	with time.	8 9	served, but it wasn't on the one that led to him drafting and formulating his opinions, putting them
9 10	with time. BY MR. THORNBURGH:	8 9 10	served, but it wasn't on the one that led to him drafting and formulating his opinions, putting them to paper, et cetera. So, that's all. I'm not
9 10 11	with time. BY MR. THORNBURGH: Q. So, if we look at the data, you'll see	8 9 10 11	served, but it wasn't on the one that led to him drafting and formulating his opinions, putting them to paper, et cetera. So, that's all. I'm not trying to argue with you.
9 10 11 12	with time. BY MR. THORNBURGH: Q. So, if we look at the data, you'll see that at one year at January 18, 2008, what was the	8 9 10 11 12	served, but it wasn't on the one that led to him drafting and formulating his opinions, putting them to paper, et cetera. So, that's all. I'm not trying to argue with you.  BY MR. THORNBURGH:
9 10 11 12 13	with time. BY MR. THORNBURGH: Q. So, if we look at the data, you'll see that at one year at January 18, 2008, what was the failure rate?	8 9 10 11 12 13	served, but it wasn't on the one that led to him drafting and formulating his opinions, putting them to paper, et cetera. So, that's all. I'm not trying to argue with you.  BY MR. THORNBURGH:  Q. Now, let's go back to P1437 really
9 10 11 12	with time.  BY MR. THORNBURGH:  Q. So, if we look at the data, you'll see that at one year at January 18, 2008, what was the failure rate?  A. Over 60%.	8 9 10 11 12 13 14	served, but it wasn't on the one that led to him drafting and formulating his opinions, putting them to paper, et cetera. So, that's all. I'm not trying to argue with you.  BY MR. THORNBURGH:  Q. Now, let's go back to P1437 really quick. What is Vincent Lucente's response?
9 10 11 12 13 14 15	with time.  BY MR. THORNBURGH:  Q. So, if we look at the data, you'll see that at one year at January 18, 2008, what was the failure rate?  A. Over 60%.  Q. Are those good results?	8 9 10 11 12 13 14 15	served, but it wasn't on the one that led to him drafting and formulating his opinions, putting them to paper, et cetera. So, that's all. I'm not trying to argue with you.  BY MR. THORNBURGH:  Q. Now, let's go back to P1437 really quick. What is Vincent Lucente's response?  MR. SNELL: Object; reading.
9 10 11 12 13 14	with time.  BY MR. THORNBURGH:  Q. So, if we look at the data, you'll see that at one year at January 18, 2008, what was the failure rate?  A. Over 60%.  Q. Are those good results?  A. No.	8 9 10 11 12 13 14	served, but it wasn't on the one that led to him drafting and formulating his opinions, putting them to paper, et cetera. So, that's all. I'm not trying to argue with you.  BY MR. THORNBURGH:  Q. Now, let's go back to P1437 really quick. What is Vincent Lucente's response?  MR. SNELL: Object; reading.  BY MR. THORNBURGH:
9 10 11 12 13 14 15 16	with time. BY MR. THORNBURGH: Q. So, if we look at the data, you'll see that at one year at January 18, 2008, what was the failure rate? A. Over 60%. Q. Are those good results? A. No. Q. And if you look at the six-month data,	8 9 10 11 12 13 14 15 16	served, but it wasn't on the one that led to him drafting and formulating his opinions, putting them to paper, et cetera. So, that's all. I'm not trying to argue with you.  BY MR. THORNBURGH:  Q. Now, let's go back to P1437 really quick. What is Vincent Lucente's response?  MR. SNELL: Object; reading.  BY MR. THORNBURGH:  Q. Is there anything relevant or
9 10 11 12 13 14 15	with time. BY MR. THORNBURGH: Q. So, if we look at the data, you'll see that at one year at January 18, 2008, what was the failure rate? A. Over 60%. Q. Are those good results? A. No. Q. And if you look at the six-month data, what was the failure rate?	8 9 10 11 12 13 14 15 16 17	served, but it wasn't on the one that led to him drafting and formulating his opinions, putting them to paper, et cetera. So, that's all. I'm not trying to argue with you.  BY MR. THORNBURGH:  Q. Now, let's go back to P1437 really quick. What is Vincent Lucente's response?  MR. SNELL: Object; reading.  BY MR. THORNBURGH:  Q. Is there anything relevant or significant to Dr. Lucente's response that you'd
9 10 11 12 13 14 15 16 17 18	with time. BY MR. THORNBURGH: Q. So, if we look at the data, you'll see that at one year at January 18, 2008, what was the failure rate? A. Over 60%. Q. Are those good results? A. No. Q. And if you look at the six-month data, what was the failure rate? A. Over 25%.	8 9 10 11 12 13 14 15 16 17 18	served, but it wasn't on the one that led to him drafting and formulating his opinions, putting them to paper, et cetera. So, that's all. I'm not trying to argue with you.  BY MR. THORNBURGH:  Q. Now, let's go back to P1437 really quick. What is Vincent Lucente's response?  MR. SNELL: Object; reading.  BY MR. THORNBURGH:  Q. Is there anything relevant or significant to Dr. Lucente's response that you'd like to discuss with the jury?
9 10 11 12 13 14 15 16 17	with time. BY MR. THORNBURGH: Q. So, if we look at the data, you'll see that at one year at January 18, 2008, what was the failure rate? A. Over 60%. Q. Are those good results? A. No. Q. And if you look at the six-month data, what was the failure rate? A. Over 25%. Q. If you look at the three-to-four-month	8 9 10 11 12 13 14 15 16 17	served, but it wasn't on the one that led to him drafting and formulating his opinions, putting them to paper, et cetera. So, that's all. I'm not trying to argue with you.  BY MR. THORNBURGH:  Q. Now, let's go back to P1437 really quick. What is Vincent Lucente's response?  MR. SNELL: Object; reading.  BY MR. THORNBURGH:  Q. Is there anything relevant or significant to Dr. Lucente's response that you'd like to discuss with the jury?  If we just orient ourselves really
9 10 11 12 13 14 15 16 17 18	with time. BY MR. THORNBURGH: Q. So, if we look at the data, you'll see that at one year at January 18, 2008, what was the failure rate? A. Over 60%. Q. Are those good results? A. No. Q. And if you look at the six-month data, what was the failure rate? A. Over 25%.	8 9 10 11 12 13 14 15 16 17 18	served, but it wasn't on the one that led to him drafting and formulating his opinions, putting them to paper, et cetera. So, that's all. I'm not trying to argue with you.  BY MR. THORNBURGH:  Q. Now, let's go back to P1437 really quick. What is Vincent Lucente's response?  MR. SNELL: Object; reading.  BY MR. THORNBURGH:  Q. Is there anything relevant or significant to Dr. Lucente's response that you'd like to discuss with the jury?  If we just orient ourselves really quick, did Dr. Lucente respond to the data that was
9 10 11 12 13 14 15 16 17 18	with time. BY MR. THORNBURGH: Q. So, if we look at the data, you'll see that at one year at January 18, 2008, what was the failure rate? A. Over 60%. Q. Are those good results? A. No. Q. And if you look at the six-month data, what was the failure rate? A. Over 25%. Q. If you look at the three-to-four-month	8 9 10 11 12 13 14 15 16 17 18 19 20	served, but it wasn't on the one that led to him drafting and formulating his opinions, putting them to paper, et cetera. So, that's all. I'm not trying to argue with you.  BY MR. THORNBURGH:  Q. Now, let's go back to P1437 really quick. What is Vincent Lucente's response?  MR. SNELL: Object; reading.  BY MR. THORNBURGH:  Q. Is there anything relevant or significant to Dr. Lucente's response that you'd like to discuss with the jury?  If we just orient ourselves really
9 10 11 12 13 14 15 16 17 18 19 20 21	with time. BY MR. THORNBURGH: Q. So, if we look at the data, you'll see that at one year at January 18, 2008, what was the failure rate? A. Over 60%. Q. Are those good results? A. No. Q. And if you look at the six-month data, what was the failure rate? A. Over 25%. Q. If you look at the three-to-four-month data, what was the success rate?	8 9 10 11 12 13 14 15 16 17 18 19 20 21	served, but it wasn't on the one that led to him drafting and formulating his opinions, putting them to paper, et cetera. So, that's all. I'm not trying to argue with you.  BY MR. THORNBURGH:  Q. Now, let's go back to P1437 really quick. What is Vincent Lucente's response?  MR. SNELL: Object; reading.  BY MR. THORNBURGH:  Q. Is there anything relevant or significant to Dr. Lucente's response that you'd like to discuss with the jury?  If we just orient ourselves really quick, did Dr. Lucente respond to the data that was

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	Page 334		Page 336
1	A. Yes.	1	A. I do recall an abstract from Stephanie
2	BY MR. THORNBURGH:	2	Molden.
3	Q. And what does Dr. Lucente indicate with	3	MR. THORNBURGH: Just give me one second.
4	respect to his concern about the TVT-Secur efficacy	4	Can we go off the record real quick.
5	when compared to Ethicon's other TVT Retropubic and	5	THE VIDEOGRAPHER: The time is 5:18 p.m. and
6	TVT-O devices?	6	we are going off the video record.
7	MR. SNELL: Objection; leading.	7	(WHEREUPON, a recess was had
8	BY THE WITNESS:	8	from 5:18 to 5:26 p.m.)
9	A. He states that "It may be our 'hard	9	THE VIDEOGRAPHER: The time is 5:26 p.m. and
10	line' definition of 'dry' versus 'success.' As you	10	we're back on the video record.
11	know for SUI in Hilton-Ward randomized controlled	11	BY MR. THORNBURGH:
12	trial Burch v TVT, the TVT success rate was 58%."	12	Q. Okay. Dr. Rosenzweig, before we went
13	BY MR. THORNBURGH:	13	off the record to break, we were looking at two
14	Q. And then he says what's the next	14	exhibits, one was P1437, which was the e-mail that
15	sentence after that?	15	contained Dr. Lucente's data and dated January 21
16	MR. SNELL: Same.	16	of 2008, and the other exhibit that we had looked
17	BY THE WITNESS:	17	at was Exhibit P784, which had just the six-week
18	A. "Nonetheless, very concerning when	18	data from Dr. Lucente's experience with the
19	compared to our TVT and TVT-O long-term dryness	19	TVT-Secur.
20	rates."	20	Do you recall that?
21	BY MR. THORNBURGH:	21	A. Yes.
22	Q. And what is the significance, if	22	Q. Okay. Now, if we look at 1437, you'll
23	anything, with respect to Dr. Lucente's response?	23	see that after Stephanie Molden circulates their
24	MR. SNELL: Object.	24	one-year data, that there's a discussion by
	Page 335		Page 337
1	BY THE WITNESS:	1	Dr. Lucente about the data concerning when compared
2	A. It shows that the TVT-Secur has a lower	2	to the TVT and TVT-O data and then if you look at
3	success rate than TVT and TVT-O.	3	the very top of this exhibit, Scott Ciarrocca of
4	BY MR. THORNBURGH:	4	Ethicon says, "Guys, I think we need to probe this
5	Q. Now, Dr. Ciarrocca responds. Do you see	5	data with him."
6	that?	6	Do you see that?
7	MR. SNELL: Object.	7	A. Yes.
8	BY THE WITNESS:	8	Q. Okay. And then I gave you
9	A. I don't know if Scott Ciarrocca is a	9	Exhibit P2225. Had you seen Exhibit P2225 before?
10	doctor.	10	MR. SNELL: I'm going to object. It's not on
11	BY MR. THORNBURGH:	11	his reliance list as far as we can tell.
12	Q. I'm sorry. Mr. Ciarrocca. Scott	12	BY MR. THORNBURGH:
13	Ciarrocca. Is he an Ethicon employee?	13	Q. Do you recall being questioned about it
14	A. Yes.	14	at the last trial?
14 15	Q. And what does Mr. Ciarrocca respond?	15	A. I do recall that, yes.
15 16	<ul><li>Q. And what does Mr. Ciarrocca respond?</li><li>A. "I think we need to probe this data with</li></ul>		<ul><li>A. I do recall that, yes.</li><li>Q. Do you recall William Gage</li></ul>
15	Q. And what does Mr. Ciarrocca respond? A. "I think we need to probe this data with him."	15 16 17	<ul><li>A. I do recall that, yes.</li><li>Q. Do you recall William Gage</li><li>cross-examined you at length concerning P2225?</li></ul>
15 16	<ul><li>Q. And what does Mr. Ciarrocca respond?</li><li>A. "I think we need to probe this data with him."</li><li>Q. Did Dr. Lucente end up publishing his</li></ul>	15 16	<ul><li>A. I do recall that, yes.</li><li>Q. Do you recall William Gage</li><li>cross-examined you at length concerning P2225?</li><li>A. I do recall that, yes.</li></ul>
15 16 17	<ul><li>Q. And what does Mr. Ciarrocca respond?</li><li>A. "I think we need to probe this data with him."</li><li>Q. Did Dr. Lucente end up publishing his data, his one-year data?</li></ul>	15 16 17	<ul> <li>A. I do recall that, yes.</li> <li>Q. Do you recall William Gage</li> <li>cross-examined you at length concerning P2225?</li> <li>A. I do recall that, yes.</li> <li>Q. Okay. And what does what does and</li> </ul>
15 16 17 18	<ul> <li>Q. And what does Mr. Ciarrocca respond?</li> <li>A. "I think we need to probe this data with him."</li> <li>Q. Did Dr. Lucente end up publishing his data, his one-year data?</li> <li>A. Not that I specifically recall.</li> </ul>	15 16 17 18	<ul><li>A. I do recall that, yes.</li><li>Q. Do you recall William Gage</li><li>cross-examined you at length concerning P2225?</li><li>A. I do recall that, yes.</li></ul>
15 16 17 18 19	<ul><li>Q. And what does Mr. Ciarrocca respond?</li><li>A. "I think we need to probe this data with him."</li><li>Q. Did Dr. Lucente end up publishing his data, his one-year data?</li></ul>	15 16 17 18 19	<ul> <li>A. I do recall that, yes.</li> <li>Q. Do you recall William Gage</li> <li>cross-examined you at length concerning P2225?</li> <li>A. I do recall that, yes.</li> <li>Q. Okay. And what does what does and</li> </ul>
15 16 17 18 19 20	<ul> <li>Q. And what does Mr. Ciarrocca respond?</li> <li>A. "I think we need to probe this data with him."</li> <li>Q. Did Dr. Lucente end up publishing his data, his one-year data?</li> <li>A. Not that I specifically recall.</li> </ul>	15 16 17 18 19 20	<ul> <li>A. I do recall that, yes.</li> <li>Q. Do you recall William Gage</li> <li>cross-examined you at length concerning P2225?</li> <li>A. I do recall that, yes.</li> <li>Q. Okay. And what does what does and is P2225 the one-year outcome abstract, published</li> </ul>
15 16 17 18 19 20 21	<ul> <li>Q. And what does Mr. Ciarrocca respond?</li> <li>A. "I think we need to probe this data with him."</li> <li>Q. Did Dr. Lucente end up publishing his data, his one-year data?</li> <li>A. Not that I specifically recall.</li> <li>Q. Do you know whether or not there is any</li> </ul>	15 16 17 18 19 20 21	<ul> <li>A. I do recall that, yes.</li> <li>Q. Do you recall William Gage</li> <li>cross-examined you at length concerning P2225?</li> <li>A. I do recall that, yes.</li> <li>Q. Okay. And what does what does and is P2225 the one-year outcome abstract, published abstract concerning Dr. Lucente and Molden's</li> </ul>

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1		l .	Page 340
	BY THE WITNESS:	1	Q. Are there any differences in the data?
2	A. Yes.	2	A. Yes.
3	BY MR. THORNBURGH:	3	MR. SNELL: Same.
4	Q. What is Exhibit P2225?	4	BY MR. THORNBURGH:
5	A. It is an abstract regarding the one-year	5	Q. What are the differences?
6	outcome data for TVT-Secur.	6	A. The dryness rate that is reported in the
7	Q. And if you turn to the last page of	7	abstract is close is approximately 70% where it
8	Exhibit P2225, you'll see there is a date that	8	is less than 40% in the internal e-mail.
9	says, "Here is updated Secur data as of April 8,	9	Q. Does that those does this have any
10	2008." Do you see that?	10	significance or importance with respect to your
11	A. Yes.	11	opinions?
12	Q. Okay. Now, Scott Ciarrocca writes to	12	MR. SNELL: Object.
13	his colleagues within Ethicon in P1437 and says,	13	BY THE WITNESS:
14	"I think we need to probe this data with him," on	14	A. We see that Scott Ciarrocca states that
15	January 21, 2008. Do you see that?	15	"We will need to probe this data with him," and we
16	A. Yes.	16	see differences even on the last page of this
17	Q. Okay. And what ultimately gets reported	17	document where they Stephanie Molden's name is
18	as the one-year data a few months later in P2225	18	below that their one-year completely dry rate is
19	concerning the one-year data that's discussed	19	reported here as 51%, here it's 70%, and in the
20	initially in P1437?	20	e-mail it's 40%.
21	MR. SNELL: Objection. Go ahead.	21	Q. Is it
22	BY MR. THORNBURGH:	22	A. So, there are a variety of different
23	Q. Side by side, but go to page 1.	23	numbers at the same time frame for the one-year
24	If you just look at if you look at	24	dryness rate.
	Page 339		
1	I'm trying to streamline this because I know	1	Q. Doctor, I didn't create these exhibits,
2	opposing counsel has to leave.	2	did I?
3	If you go to under the "Results"	3	A. No.
4	section, beginning with, "There was significant	4	MR. SNELL: Objection.
5	decrease in dryness."	5	BY MR. THORNBURGH:
6	A. Yes.	6	Q. Whose exhibits do they belong to? Whose
7	MR. THORNBURGH: Go ahead and blow that up,	7	documents do these belong to?
8	Tom.	8	A. These are internal Ethicon documents.
9	BY MR. THORNBURGH:	9	Q. Doctor, is it ever appropriate
10	Q. And highlight beginning with midway	10	MR. SNELL: Objection; misstates the evidence.
11	through where it says, "There was significant	11	BY MR. THORNBURGH:
12	decrease in dryness rate from two weeks 91.3% to	12	Q. Is it ever appropriate for a medical
13	one year postoperatively 69%."	13	device company who receives concerning information
14	Do you see that?	14	about the efficacy of its medical devices to
15	A. Yes.	15	intervene with the researchers of the data and get
16	MR. SNELL: Object; leading.	16	that data changed?
17	BY MR. THORNBURGH:	17	MR. SNELL: Objection and misstates the
18	Q. So, behind closed doors strike that.	18	evidence.
19	Do you see any differences between what	19	BY THE WITNESS:
20	was being discussed internally in Ethicon's e-mails	20	A. No.
21	with Dr. Lucente versus what ultimately got	21	BY MR. THORNBURGH:
	published?	22	Q. Why not?
22	published:		
22 23	MR. SNELL: Object.	23	A. Because doctors should be given complete

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-	Page 342		Page 344
1	complications associated with the medical device.	1	Is there anything significant with that
2	Q. If the one-year data showed a failure	2	fact to your opinions?
3	rate of greater than 60%, should Ethicon have	3	MR. SNELL: Object.
4	described or should these strike that.	4	BY THE WITNESS:
5	If the if the accurate information at	5	A. Well, in the e-mail they're talking
6	one year for Dr. Molden and Lucente's data was a	6	about 247 patients. In this document from
7	failure rate of or success rate of only 38.5%, is	7	Stephanie Molden the N is 267 patients. And in the
8	that the data that should have been disclosed to	8	abstract, which seems to have included another
9	physicians?	9	physician beside Dr. Lucente's data, Dr. Olson,
10	MR. SNELL: Objection and misstates the	10	because you see that this is data collected at two
11	evidence.	11	different hospitals, the total number of patients
12	BY THE WITNESS:	12	that underwent the Secur were 349 patients but only
13	A. That would have been important data to	13	149 were evaluated at one year.
14	disclose to physicians.	14	So, it's really difficult to say the
15	BY MR. THORNBURGH:	15	exact data set that they're looking at, but there
16	Q. And by disclosing data that shows a	16	are differences in the numbers that are reported.
17	higher efficacy rate, does that or does that	17	Q. And are there ways to pull data that
18	does that in any way impact potentially the	18	could provide inaccurate information?
19	risk/benefit assessment that physicians perform	19	MR. SNELL: Objection.
20	when deciding which treatment options to recommend	20	BY THE WITNESS:
21	to their patients?	21	A. Correct.
22	MR. SNELL: Object.	22	BY MR. THORNBURGH:
23	BY THE WITNESS:	23	Q. In other words, if you if you knew
24	A. It would be difficult for a doctor to	24	that your results were poor and you had a 30
24	A. It would be difficult for a doctor to	24	that your results were poor and you had a 50
	Page 343		Page 345
1	accurately give a risk/benefit analysis to their	1	
2		_	only a 38% success rate, could you add some other
	patient if they're not provided with accurate	2	doctors' patients to your pool who had a better
3	patient if they're not provided with accurate information regarding the risks and benefits		
		2	doctors' patients to your pool who had a better
3	information regarding the risks and benefits	2 3	doctors' patients to your pool who had a better success rate to increase your numbers, to make your
3 4	information regarding the risks and benefits associated with a medical device.	2 3 4	doctors' patients to your pool who had a better success rate to increase your numbers, to make your numbers look better?
3 4 5	information regarding the risks and benefits associated with a medical device. BY MR. THORNBURGH:	2 3 4 5	doctors' patients to your pool who had a better success rate to increase your numbers, to make your numbers look better?  MR. SNELL: Objection.
3 4 5 6	information regarding the risks and benefits associated with a medical device.  BY MR. THORNBURGH:  Q. Now, did Dr based on the exhibits that we just looked at, P2225, P1437, and P1437,	2 3 4 5 6	doctors' patients to your pool who had a better success rate to increase your numbers, to make your numbers look better?  MR. SNELL: Objection. BY THE WITNESS:  A. Possibly.
3 4 5 6 7	information regarding the risks and benefits associated with a medical device.  BY MR. THORNBURGH:  Q. Now, did Dr based on the exhibits that we just looked at, P2225, P1437, and P1437, did Dr. Molden and Dr. Lucente's data get better or	2 3 4 5 6 7	doctors' patients to your pool who had a better success rate to increase your numbers, to make your numbers look better?  MR. SNELL: Objection. BY THE WITNESS:
3 4 5 6 7 8	information regarding the risks and benefits associated with a medical device.  BY MR. THORNBURGH:  Q. Now, did Dr based on the exhibits that we just looked at, P2225, P1437, and P1437, did Dr. Molden and Dr. Lucente's data get better or worse after Mr. Ciarrocca of Ethicon said that they	2 3 4 5 6 7 8	doctors' patients to your pool who had a better success rate to increase your numbers, to make your numbers look better?  MR. SNELL: Objection. BY THE WITNESS:  A. Possibly.  MR. THORNBURGH: I think did you guys want to break now?
3 4 5 6 7 8 9	information regarding the risks and benefits associated with a medical device.  BY MR. THORNBURGH:  Q. Now, did Dr based on the exhibits that we just looked at, P2225, P1437, and P1437, did Dr. Molden and Dr. Lucente's data get better or worse after Mr. Ciarrocca of Ethicon said that they needed to probe Dr. Lucente's data with him?	2 3 4 5 6 7 8	doctors' patients to your pool who had a better success rate to increase your numbers, to make your numbers look better?  MR. SNELL: Objection. BY THE WITNESS:  A. Possibly.  MR. THORNBURGH: I think did you guys want
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1	the take-home message from TVT-Secur, "It is	1
2	completely different from TVT and TVT-O." The	I, CORINNE T. MARUT, C.S.R. No. 84-1968,
3	you have to "live through the learning curve of 20	2 Registered Professional Reporter and Certified Shorthand Reporter, do hereby certify:
4	cases," and the learning curve can be as long as 5	3 That previous to the commencement of the examination of the witness, the witness was duly
5	to 20 weeks.	4 sworn to testify the whole truth concerning the matters herein;
6	BY MR. THORNBURGH:	5 That the foregoing deposition transcript
7	Q. And why are those those issues that	was reported stenographically by me, was thereafter reduced to typewriting under my personal direction
8	you identified significant to your opinions?	and constitutes a true record of the testimony given and the proceedings had;
9	A. It is completely different from the TVT	That the said deposition was taken
10	and TVT-O. Therefore, you cannot use the TVT and	8 before me at the time and place specified; That the reading and signing by the
11	TVT-O data to state that the TVT-Secur will have	9 witness of the deposition transcript was agreed upon as stated herein;
12		10 That I am not a relative or employee or
13	the same data because it is a completely different	attorney or counsel, nor a relative or employee of  such attorney or counsel for any of the parties
14	product and the length of the learning curve shows	hereto, nor interested directly or indirectly in the outcome of this action.
15	that there is a defect in the Instructions for Use.	It was requested before completion of
16	Q. Any other significant information from	the deposition that the witness, BRUCE ALAN ROSENZWEIG, M.D., have the opportunity to read and
	Exhibit 784 that you want to discuss?	14 sign the deposition transcript. 15
17	A. No.	
18	MR. THORNBURGH: I think that concludes the	17
19	day.	(The foregoing certification of this  18 transcript does not apply to any
20	MR. SNELL: All right.	reproduction of the same by any means, unless under
21	MR. THORNBURGH: Thank you, Doctor.	certifying reporter.)
22	THE VIDEOGRAPHER: Okay. Shall I go off the	20 21
23	record?	22 23
24	MR. THORNBURGH: Sure.	24
	Page 347	
	rage 347	Page 349
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88 (Pages 346 to 349)